

InterStim_Bowel_en_fcw.fm 8/14/08 1:40 pm
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INFORMATION FOR PRESCRIBERS

Medtronic InterStim® Therapy

Rx only

M925905A003 Rev X

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Additional information available for the InterStim Therapy system

Documents packaged with this product:

- For therapy-specific information, refer to the *Indications Insert*.
- For information regarding device compatibility, refer to the *System Overview and Compatibility Insert*.
- For information on the clinical study results for InterStim Therapy and for a complete summary of adverse events, refer to the *Clinical Summary*.
- For warranty information, refer to the *Limited Warranty and Special Notice Insert*.

Documents packaged with the clinician programmer software application card:

- For neurostimulator selection, battery longevity calculations, and specific neurostimulator specifications, refer to the *System Eligibility, Battery Longevity, Specifications Reference Manual*.

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Contraindications

Implantation of an InterStim neurostimulation system is contraindicated for the following patients:

- Patients who have not demonstrated an appropriate response to test stimulation; or
- Patients who are unable to operate the neurostimulator.

After implantation of any system component, the following contraindication applies:

Diathermy – Do not use shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death. For more information about diathermy refer to Table 1 on page 6 and to "Appendix A: Electromagnetic interference" beginning on page 15.

Warnings

Electromagnetic interference (EMI)

Electromagnetic interference is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with neurostimulator function. Neurostimulators include features that provide protection from electromagnetic interference. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a neurostimulator. However, sources of strong electromagnetic interference can result in the following:

- **Serious patient injury or death**, resulting from heating of the implanted components of the neurostimulation system and damage to surrounding tissue.
- **System damage**, resulting in a loss of or change in symptom control and requiring surgical replacement.
- **Operational changes to the neurostimulator**, causing it to turn on or off (particularly in Model 3023 Neurostimulators, which are enabled for magnet use), or to reset to power-on-reset (POR) settings, resulting in loss of stimulation, return of symptoms, and in the case of POR, requiring reprogramming by a clinician.
- **Unexpected changes in stimulation**, causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation may feel uncomfortable, it does not damage the device or injure the patient directly. In rare cases, as a result of the unexpected change in stimulation, patients have fallen down and been injured.

For information on sources of EMI, the effect of EMI on the patient and the neurostimulation system, and instructions on how to reduce the risks from EMI, refer to Table 1 on page 6, and "Appendix A: Electromagnetic Interference" beginning on page 15.

For information about the effects of EMI on programming, refer to "Telemetry signal disruption from EMI" beginning on page 8.

Table 1. Potential effects of EMI from devices or procedures

Medical procedure	Patient injury	Device damage	Other possible effects			See guidelines
			Momentary increase in stimulation	Turns device on or off	Intermittent stimulation	
Bone growth stimulators			*		*	page 18
Defibrillation/cardioversion	*	*	*		*	page 15
Dental drills and probes		*				page 18
Diathermy, therapeutic ^a	*	*			*	page 5
Electrocautery	*	*				page 16
Electrolysis		*			*	page 19
Electromagnetic field devices: (eg, arc welding, power stations)			*	*	*	page 19
High-output ultrasonics/lithotripsy		*				page 16
Household items			*	*		page 20
Laser procedures		*				page 19
Magnetic resonance imaging (MRI)	*	*	*	*	*	page 17
Psychotherapeutic procedures	*	*	*	*	*	page 19
Radiation therapy	*	*				page 19
Radiofrequency (RF)/microwave ablation	*	*			*	page 16
Theft detector	*		*	*	*	page 17
Therapeutic magnets				*		page 20
Therapeutic ultrasound ^a	*	*			*	page 15
Transcutaneous electrical nerve stimulation (TENS)			*	*		page 20

^a Diathermy and therapeutic ultrasound procedures are contraindicated for patients who have an InterStim Therapy system. See page 5 for more information.

Case Damage

If the neurostimulator case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

Effects on other implanted devices

The neurostimulation system may affect the operation of other implanted devices, such as cardiac devices, other neurostimulators, and implantable drug pumps. Physical proximity may cause sensing problems and inappropriate device responses. Clinicians involved with both devices should evaluate any potential interference problems before surgery. Careful programming of each system may be necessary to optimize the patient's benefit from each device.

Neurostimulator interaction with implanted cardiac devices

When a patient's medical condition requires both a neurostimulator and an implanted cardiac device (eg, pacemaker, defibrillator), clinicians involved with both devices (eg, neurologist, neurosurgeon, cardiologist, electrophysiologist, urologist, urogynecologist, cardiac surgeon) should discuss the possible interactions between the devices before surgery. To minimize or prevent the effects described below, implant the devices on opposite sides of the body and follow any additional instructions.

- Defibrillation therapy from an implanted defibrillator may damage the neurostimulator.
- The electrical pulses from the neurostimulation system may interact with the sensing operation from cardiac devices and could result in an inappropriate response of the cardiac devices. To minimize or prevent the cardiac device from sensing the neurostimulator output, program the neurostimulator to a bipolar configuration and to a minimum rate of 60 Hertz. Program the cardiac device to bipolar sensing.

See also: "Programmer interaction with other active implanted devices" beginning on page 8.

Precautions

Clinician programming

Battery depletion – Patients with very low stimulation thresholds may feel more intense stimulation as the neurostimulator battery nears total depletion. Patients should be told that as their neurostimulator battery approaches total depletion, they may need to adjust their stimulation amplitude more often to maintain the desired level of stimulation.

Clinician programmer compatibility – The clinician programmer can only be used to program Medtronic neurological devices that correspond with a Medtronic therapy application software such as the software on the InterStim Model 8870 Application Card.

Magnet compatibility – The Model 8529 Magnet is for use with Medtronic pumps only. If the clinician programmer has a Model 8529 Magnet attached, remove the magnet before approaching a patient who has an implanted neurostimulator or other implanted medical device (such as a pacemaker or defibrillator). If the magnet is too close to another implanted device, the therapy of the other device may change.

Parameter adjustment – Do the following to prevent an abrupt change in stimulation, which some patients have described as uncomfortable stimulation (jolting or shocking sensation):

- Program parameter changes in small increments.
- Enable SoftStart/SoftStop mode whenever possible.
- Decrease the amplitude to 0.0 V before taking these actions:¹
 - Connecting the screener cable to the screener.
 - Turning off the neurostimulator or screener.
 - Turning on the neurostimulator or screener.

Sensitivity to stimulation – Patients with extremely high sensitivity to stimulation may sense the transmission of the programming signals from the programmer to the neurostimulator via radio-frequency (RF) telemetry.

Programmer interaction with a cochlear implant – When the patient has a cochlear implant, minimize or eliminate the potential for unintended audible clicks during telemetry by keeping the external portion of the cochlear system as far from the programming head as possible or by turning off the cochlear implant during programming.

Programmer interaction with flammable atmospheres – The programmer is not certified for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the programmer near flammable atmospheres are unknown.

Programmer interaction with other active implanted devices – When a patient has a neurostimulator and another active implanted device (eg, pacemaker, defibrillator, neurostimulator) the following may occur:

- The radio-frequency (RF) signal used to program these devices may reset or reprogram the other device.
- The magnet in a cardiac programmer may activate the magnetically controlled on/off switch (Model 3023 neurostimulator only).

To verify that inadvertent programming did not occur, clinicians familiar with each device should check the programmed parameters of each device before the patient is discharged from the hospital and after each programming session of either device (or as soon as possible after these times). Also, inform patients to contact their clinician immediately if they experience symptoms that could be related to either device or to the medical condition treated by either device.

Telemetry signal disruption from EMI – Do not attempt telemetry near equipment that may generate electromagnetic interference (EMI). EMI may cause a disruption in programmer function. If EMI disrupts programming, move the programmer and the neurostimulator away from the likely source of EMI. Examples of sources of EMI are magnetic resonance imaging (MRI), lithotripsy, computer monitors, cellular telephones, x-ray equipment, and other electronic equipment (See Appendix A: Electromagnetic Interference).

Sterile field – When using the programmer in a sterile field, place the programmer, programming head, and extendable cord into a sterile bag. The programmer is not sterile and cannot be sterilized.

¹ The most recent software versions MMB and NNB automatically set the amplitude lower limit to zero.

Amplitude lower limit – If your programmer is using the previous version (MMA or NNA), program the amplitude lower limit to 0.0 V.¹ This will prevent the patient from experiencing unexpected or uncomfortable stimulation (eg, shocking, jolting) when turning the device on, due to the abrupt change in stimulation.

Clinician training

Refer to the *Indications Insert* for therapy-specific training precautions.

Patient activities

Activities requiring excessive twisting or stretching – Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation system. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause component fracture or dislodgement. Component fracture or dislodgement may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component. Examples of such activities include gymnastics, mountain biking, and other sports or equipment that involve the movements described above. Ask your patients about the activities they are involved in and inform them of activity restrictions.

Antenna use – For antennas that attach to the skin, if swelling or redness occurs near the attachment site, advise the patient to contact the clinician before using the antenna again. Swelling or redness may indicate an infection or an allergic reaction to the antenna.

Component manipulation by patient (twiddler's syndrome) – Patients should avoid manipulating or rubbing the neurostimulation system through the skin. Manipulation may cause component damage, lead dislodgement, skin erosion, or uncomfortable stimulation at the implant site.

Scuba diving or hyperbaric chambers – Patients should not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters (33 feet) of water (or above 2.0 ATA) could damage the neurostimulation system. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their clinician.

Skydiving, skiing, or hiking in the mountains – High altitudes should not affect the neurostimulator, however, the patient should consider the movements involved in any planned activity and take precaution to avoid putting undue stress on the implanted system. Patients should be aware that during skydiving, the sudden jerking that occurs when the parachute opens may cause lead dislodgement or fractures, which may require surgery to reposition or replace the lead.

Unexpected changes in stimulation – Electromagnetic interference, postural changes, and other activities may cause a perceived increase in stimulation, which some patients have described as uncomfortable stimulation (jolting or shocking sensation); therefore, patients should reduce the amplitude to the lowest setting and turn off the neurostimulator before engaging in activities that could be unsafe for themselves or others if they received

¹ The most recent software versions MMB and NNB automatically set the amplitude lower limit to zero.

an unexpected jolt or shock (eg, driving, operating power tools). Patients should discuss these activities with their clinician.

Patient programming and patient control devices

Neurostimulator battery depletion – Patients with a very low perception threshold (the amplitude at which the patient first perceives stimulation) may feel the stimulation intensity fluctuate as the battery nears depletion. To compensate for this fluctuation, patients may need to decrease or increase the amplitude more often to maintain the desired level of symptom control.

Patient access to a control device – Patients must carry a patient control device at all times to have the capacity to adjust and/or turn off the neurostimulator.

Patient control devices may affect other implanted devices – Patients should not place a control device (patient programmer or control magnet) over another active implanted medical device (eg, pacemaker, defibrillator, another neurostimulator). The patient control devices could unintentionally change the operation of the other device.

Patient magnet control feature disabled (Model 3023 only) – If the magnet control feature has been disabled, the patient must carry their patient programmer with them at all times so that they can turn the neurostimulator on or off.

Patient magnet may damage items (Model 3023 only) – Patients should not place the patient magnet on or near computers, computer monitors, magnetic storage disks or tapes, televisions, cellular phones, electronic personal information managers, credit cards, or other items affected by strong magnetic fields. If the patient magnet is too close, these items may be damaged.

Patient programmer handling – To avoid damaging the patient programmer, patients should not immerse it in liquid, clean it with bleach, nail polish remover, mineral oil, or similar substances; and should not drop it or mishandle it in a way that may damage it.

Patient programmer use – When operating a patient programmer, patients should use special care near flammable or explosive atmospheres. An interaction between the flammable or explosive atmospheres and the battery in the programmer could occur. The consequences of using a battery-powered programmer near flammable or explosive atmospheres are unknown.

Storage and sterilization

Component packaging – Do not implant a component if any of the following have occurred:

- The storage package or sterile pack has been pierced or altered, because component sterility cannot be guaranteed and infection may occur.
- The component shows signs of damage, because the component may not function properly.
- The use-by date has expired, because component sterility cannot be guaranteed and infection may occur; also, neurostimulator battery longevity may be reduced and may require early replacement.

Sterilization – Medtronic has sterilized the package contents according to the process indicated on the package label before shipment. This device is for single use only and is not intended to be resterilized.

Storage temperature: leads and extensions – Do not store or transport the lead or extension above 57°C (135°F) or below -34°C (-30°F). Temperatures outside this range can damage components.

Storage temperature: neurostimulators – Do not store or transport the neurostimulator above 52°C (125°F) or below -18°C (0°F). Temperatures outside this range can damage components.

Storage temperature: programmers and application card – The recommended storage temperature range for the programmers and application card is -40°C to 65°C (-40°F to 149°F).

The recommended operating temperature range is 10°C to 40°C (48°F to 105°F). If the programmers or application card were stored at temperatures outside of the operating range, allow the equipment to stabilize to a temperature within the range before using it.

System implant

Compatibility, all components – Follow these guidelines when selecting system components:

- **Medtronic components:** For proper therapy, use only components that are compatible with the applicable neurostimulator and indication. Compatible Medtronic components are listed in the *System Overview and Compatibility Insert*.
- **Non-Medtronic components** – The use of non-Medtronic components with the neurostimulation system may result in damage to Medtronic components, loss of stimulation, or patient injury.

Use of non-Medtronic components may void Medtronic warranty coverage.

Component failures – A neurostimulation system may fail at any time due to random failure of the system components or the battery (prior to depletion). These events, which can include electrical shorts, open circuits, and insulation breaches, cannot be predicted. In addition, all neurostimulators will ultimately cease to function.

Component handling – Handle the implantable components of this system with extreme care. These components may be damaged by excessive traction or sharp instruments, which may result in intermittent or loss of stimulation, requiring surgical replacement.

Refer to the appropriate implant manual for additional instructions.

Neurostimulator location – Select a location that meets the following criteria:

- Is a minimum of 20 cm (8 in) away from another neurostimulator to minimize telemetry interference and possible inappropriate therapy.
- Is on the opposite side of the body from another active implanted device (eg, pacemaker, defibrillator) to minimize possible interaction between the devices.
- Is away from bony structures (eg, 3 – 4 cm [1.2 – 1.6 in]) to minimize discomfort at the neurostimulator site.
- Is away from areas of restriction or pressure to minimize the potential for skin erosion, patient discomfort, or damage to components.
- Is in an area accessible to the patient for proper operation of a patient control device (ie, patient programmer, control magnet, or with use of any optional remote antenna with a patient programmer).

Use in specific populations

Refer to the *Indications Insert* for therapy-specific precautions related to specific populations.

Individualization of Treatment

Best results are achieved when the patient is fully informed about the therapy risks and benefits, surgical procedure, follow-up requirements, and self-care responsibilities. Maximum benefits from the neurostimulation system require long-term postsurgical management.

Patient selection – Select patients carefully to ensure that they meet the following criteria:

- They are appropriate candidates for surgery.
- They can properly operate the system.
- They received satisfactory results from test stimulation.

Adverse Events

In addition to the risks normally associated with surgery, implantation, or use of a neurostimulation system includes, but is not limited to, the following risks. Certain adverse events may necessitate surgical intervention.

- Adverse change in voiding function (bowel and/or bladder)
- Allergic or immune system response to the implanted materials that could result in device rejections
- Change in sensation of stimulation which has been described as uncomfortable (jolting or shocking) by some patients
- Infection
- New pain
- Pain at neurostimulator and or lead site
- Seroma, hemorrhage, hematoma, and/or paralysis
- Suspected lead or neurostimulator migration or erosion
- Suspected nerve injury
- Suspected technical device problem
- Transient electric shock

For a comprehensive summary of adverse events, refer to the *Clinical Summary*.

Patient Counseling Information

Clinicians should:

- Provide patients with the following:
 - Information about the components of the neurostimulation system.
 - Instructions for using the patient programmer and magnet (Model 3023 Neurostimulator only).
- Give the patient the *InterStim Therapy Patient Guide* and at a minimum, review these sections with the patient:
 - Living with your InterStim system
 - Information for your doctors
- Instruct patients to always do as follows:
 - Always inform healthcare professionals, such as clinicians and dentists, that they have an implanted neurostimulation system. Patients should bring their InterStim Therapy Patient Guide to all medical and dental appointments to help them answer questions that the healthcare professional may have regarding medical procedures and potential device interactions.
 - Always carry a patient control device to be able to adjust and/or turn off the neurostimulator.
 - Always bring their patient programmer to InterStim Therapy-related appointments.
 - Contact their clinician if they notice any unusual symptoms or signs.

Component Disposal

When explanting neurostimulation system components (eg, replacement, cessation of therapy, or postmortem), or when disposing of accessories, follow these guidelines:

- If possible, return the explanted component with completed paperwork to Medtronic for analysis and disposal.
- To allow for device analysis, do not autoclave the device or expose the device to ultrasonic cleaners.
- Dispose of any components not returned to Medtronic according to local environmental regulations; in some countries, explanting a battery-operated implantable device is mandatory.

Cautions:

- Follow appropriate biohazard controls for all explanted components or components coming into contact with bodily fluids. Only return such components to Medtronic in the appropriate packaging supplied by Medtronic.
- Do not incinerate or cremate the neurostimulator because it may explode if subjected to these temperatures.
- Do not reuse any implantable device or implantable accessory after exposure to body tissues or fluids because the sterility and functionality of the component cannot be guaranteed.

Appendix A: Electromagnetic Interference

Please review Electromagnetic interference (EMI) under "Warnings" beginning on page 5 and Table 1 "Potential effects of EMI from devices or procedures" beginning on page 6.

Before any medical procedure is begun, patients should always inform any healthcare personnel that they have an implanted neurostimulation system. The potential for the following effects results from an interaction of the neurostimulation system and equipment—even when both are working properly.

Contraindication

Diathermy – Do not use shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy can also damage the neurostimulation system components, resulting in loss of therapy and requiring additional surgery for system explantation and replacement. Advise your patient to inform all their healthcare professionals that they should not be exposed to diathermy treatment.

Injury to the patient or damage to the device can occur during diathermy treatment in the following instances:

- The neurostimulation system is turned on or off.
- Diathermy is used anywhere on the body—not just at the location of the neurostimulation system.
- Diathermy delivers heat or no heat.
- Any component of the neurostimulation system (lead, extension, neurostimulator) remains in the body.

Warnings

EMI from various sources may damage the device, interfere with device operation, or cause harm to the patient. Please consider the following:

Defibrillation or cardioversion – When a patient is in ventricular or atrial fibrillation, the first consideration is patient survival. External defibrillation or cardioversion can damage a neurostimulation system and cause induced currents in the lead-extension portion of the neurostimulation system that can injure the patient. Minimize the current flowing through the neurostimulator system by following these guidelines:

- Position defibrillation paddles as far from the neurostimulator as possible.
- Position defibrillation paddles perpendicular to the neurostimulation system.
- Use the lowest clinically appropriate energy (joules) output (watt seconds).

After defibrillation, confirm the neurostimulation system is functioning as intended.

Electrocautery – If electrocautery is used near an implantable device or contacts a device or insertion-needle, the following effects may occur:

- The tissue surrounding the insertion-needle (during placement of a percutaneous lead) may be damaged.
- The insulation on the lead or extension may be damaged, resulting in component failure or induced currents into the patient that may damage tissue or stimulate or shock the patient. If this occurs, do not use the damaged component. Obtain a new component from Medtronic for use.
- The neurostimulator may be damaged, output may be temporarily suppressed or increased, or stimulation may stop because parameters were changed to power-on-reset (POR) settings (ie, output off, amplitude 0.0 V). If this occurs check the neurostimulator using the clinician programmer and reprogram all parameters to their intended settings. See the neurostimulator technical manual for POR settings and remedial actions.

When electrocautery is necessary, follow these precautions:

- Before using electrocautery, turn off the neurostimulator.
- Use only bipolar cautery.
- Disconnect any cable connecting the lead or extension to a screener or external neurostimulator.
- If unipolar cautery is necessary, follow these guidelines:
 - Use only a low-voltage mode.
 - Use the lowest possible power setting.
 - Keep the current path (ground plate) as far from the neurostimulator, extension, and lead as possible.
 - Do not use full-length operating room table grounding pads.
- After using electrocautery, confirm that the neurostimulator is functioning as intended.

High-output ultrasonics or lithotripsy – Use of high-output ultrasonic devices, such as electrohydraulic lithotriptors, is not recommended for patients who have an implanted neurostimulation system. While there is no danger to the patient, exposure to high-output ultrasonic frequencies may result in damage to the neurostimulator circuitry. If lithotripsy must be used, do not focus the beam within 15 cm (6 in) of the neurostimulator.

Radiofrequency (RF) or microwave ablation – Safety has not been established for RF or microwave ablation in patients who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

Magnetic resonance imaging (MRI) – MRI is not recommended for a patient who has any implanted component of a neurostimulation system. Exposing a patient with an implanted neurostimulation system or component to MRI may potentially injure the patient or damage the neurostimulator. Clinicians should carefully weigh the decision to use MRI in patients with an implanted neurostimulation system, and note the following:

- Induced electrical currents from the MRI to the neurostimulation system or component may cause heating, especially at the lead electrode site, resulting in tissue damage. Induced electrical currents may also stimulate or shock the patient.

Note: This warning applies even if only a lead or extension is implanted.

Factors that increase the risks of heating and patient injury include, but are not limited to, the following:

- High MRI Specific Absorption Rate (SAR) Radio Frequency (RF) power levels.
- MRI RF transmit coil that is near or extends over the implanted lead.
- Implanted leads with small surface area electrodes.
- Short distances between lead electrodes and tissue that is sensitive to heat.
- An MRI may permanently damage the neurostimulator, requiring it be removed or replaced.
- An MRI may affect the normal operation of the neurostimulator. An MRI can also reset the neurostimulator to power-on-reset (POR) values requiring reprogramming by a trained InterStim clinician.
- The neurostimulator can move within the implant pocket and align with the MRI field, resulting in discomfort or reopening of a recent implant incision.

In addition, the image details from MRI may be degraded, distorted, or blocked from view by the implanted neurostimulation system.

Patients treated with MRI should be closely monitored and programmed parameters verified upon cessation of MRI.

Effects of monitoring devices – When using diagnostic monitoring devices such as an electrocardiogram (ECG), Holter Monitor, electroencephalogram (EEG); or implantable heart monitor, pulses from the neurostimulation system may be detected as an electrical signal. When evaluating the diagnostic information, be sure to identify the neurostimulator pulses as intrinsic.

Theft detectors and security screening devices – Theft detectors found in retail stores, public libraries, etc., and security screening devices found in airports, government buildings, etc., occasionally may cause intermittent stimulation or a momentary increase in stimulation intensity. When they pass through these devices, some patients may perceive intermittent stimulation as switching their neurostimulation system on and off. It is also possible that patients, especially those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation when they pass through these devices. Higher levels of stimulation have been described as uncomfortable ("jolting" or "shocking") by some patients. In rare situations, such occurrences have caused patients to fall, potentially causing personal injury.

When approaching these devices, patients should do the following:

1. If possible, request to bypass these devices. Patients should show the security personnel their patient identification card for the neurostimulator and request a manual search. Security personnel may use a handheld security wand but patients should ask the security personnel not to hold the security wand near the neurostimulator any longer than is absolutely necessary. Patients may wish to ask for another form of personal search.
2. If patients must pass through the theft detector or security screening device, they should turn off their neurostimulator, approach the center of the device and walk through normally (Figure 1).
 - a. If two security gates are present, they should walk through the middle, keeping as far from each gate as possible.
 - b. If one gate is present, they should walk as far from it as possible.

Note: Some theft detectors and screening devices may not be visible.
3. Proceed through the security device. Patients should not linger near or lean on the screening device.

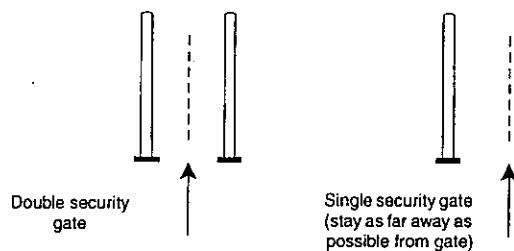


Figure 1. Approaching security gates.

4. After patients pass through the security device, they should turn on their neurostimulator.

Precautions

EMI from the following equipment is unlikely to affect the neurostimulation system if the guidelines below are followed:

Bone growth stimulators – Keep external magnetic field bone growth stimulator coils 45 cm (18 in) away from the neurostimulation system. When using either an implantable or external bone growth stimulator, ensure that both the bone stimulator and neurostimulator are working as intended.

Dental drills and ultrasonic probes – Turn off the neurostimulator. Keep the drill or probe 15 cm (6 in) away from the neurostimulator.

Electrolysis – Turn off the neurostimulator. Keep the electrolysis wand at least 15 cm (6 in) away from the neurostimulator.

Electromagnetic field devices – Patients should exercise care or avoid the following equipment or environments:

- Antenna of citizens band (CB) radio or ham radio
- Electric arc welding equipment
- Electric induction heaters such as those used in industry to bend plastic
- Electric steel furnaces
- High-power amateur transmitters
- High-voltage areas (generally safe if outside the fenced area)
- Linear power amplifiers
- Magnetic degaussing equipment
- Magnets or other equipment that generates strong magnetic fields
- Microwave communication transmitters (generally safe if outside the fenced area)
- Perfusion systems
- Resistance welders
- Television and radio transmitting towers (generally safe if outside the fenced area)

If patients suspect that equipment is interfering with neurostimulator function, they should do the following:

1. Move away from the equipment or object.
2. If possible, turn off the equipment or object.
3. Then, if necessary, use the control magnet or patient programmer to return the neurostimulator to the desired on or off state. Use the patient programmer to check or adjust output amplitude.
4. Inform the equipment owner or operator of the occurrence.

If the above actions do not resolve the effects of the interference, or the patients suspect that their therapy is not effective after exposure to EMI, they should contact their clinician.

Laser procedures – Turn off the neurostimulator. Keep the laser directed away from the neurostimulation system.

Psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (eg, electroconvulsive therapy, transcranial magnetic stimulation) in patients who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

Radiation therapy – Do not direct high radiation sources such as cobalt 60 or gamma radiation at the neurostimulation system. If radiation therapy is required near the neurostimulation system, place lead shielding over the device to help prevent radiation damage.

Transcutaneous electrical nerve stimulation (TENS) – Do not place TENS electrodes so that the TENS current passes over any part of the neurostimulation system. If patients feel that the TENS may be interfering with the implanted neurostimulator, they should discontinue using the TENS until they talk with their clinician.

Notes

Household Items – Most household appliances and equipment that are working properly and grounded properly will not interfere with the neurostimulation system. The following equipment is generally safe if patients follow these guidelines:

- **Freezer, refrigerator, or storm door magnets that hold the door closed:** Do not lean against the magnetic strip of the door.
- **Radio-frequency sources (AM/FM radios, analog and digital cellular telephones, cordless and conventional telephones):** Keep these items at least 10 cm (4 in) away from the implanted neurostimulator.
- **Stereo speakers and radios for the home or car:** Do not lift or carry speakers or radios near the neurostimulator.
- **Sewing machines or salon hair dryer:** Keep the neurostimulator away from the motors.
- **Computer disk drives:** Keep the neurostimulator away from the disk drives.
- **Induction range:** Keep the neurostimulator away from the burners while the burners are turned on.
- **Power tools:** Keep the motors away from the neurostimulator, lead, and extension.

Other medical procedures – EMI from the following medical procedures is unlikely to affect the neurostimulation system:

- Computerized axial tomography (CT or CAT) scans.
- Diagnostic ultrasound (eg, carotid scan, Doppler studies).

Note: To minimize potential image distortion, turn off the neurostimulator and keep the transducer 15 cm (6 in) away from the neurostimulation system. Ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulator or implanted lead if used directly over the neurostimulator or lead implant site.

- Diagnostic x-rays or fluoroscopy

Note: External pressure used during some medical procedures may damage the neurostimulator or disconnect the neurostimulation system components, which may require surgery to reconnect or replace components. During x-ray procedures that require external compression around implanted components, the x-ray equipment should be adjusted to limit the amount of pressure exerted on the neurostimulator.

- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans

Therapeutic magnets (eg, magnetic mattresses, blankets, wrist wraps, elbow wraps) – Keep the magnet at least 25 cm (10 in) away from the neurostimulator. Magnetic fields of 10 gauss or less will generally not affect the neurostimulator.

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US Market Release
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INDICATIONS INSERT

Medtronic InterStim® Therapy

Rx only

MA12896A002 Rev X

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Additional Information available for the InterStim Therapy system

Documents packaged with this product:

- For general system information, including contraindications, warnings, precautions, resterilization, component disposal, adverse events, patient counseling, and electromagnetic interference information, refer to the *Information for Prescribers (IFP) Manual*.
- For information regarding device compatibility, refer to the *System Overview and Compatibility Insert*.
- For information on the clinical study results for InterStim Therapy and for a complete summary of adverse events, refer to the *Clinical Summary*.
- For warranty information, refer to the *Limited Warranty and Special Notice Insert*.

Documents packaged with the clinician programmer software application card:

- For neurostimulator selection, battery longevity calculations, and specific neurostimulator specifications, refer to the *System Eligibility, Battery Longevity, Specifications Reference Manual*.

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InterStim Therapy for urinary control

Indications

InterStim Therapy for urinary control is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

Warning



Warning: This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

Precautions

Clinician training

- **Implanting clinicians** should be trained on the implantation and use of the InterStim Neurostimulation System.
- **Prescribing clinicians** should be experienced in the diagnosis and treatment of lower urinary tract symptoms and should be trained on the use of the InterStim Neurostimulation System.

Use in specific populations

The safety and effectiveness of this therapy has not been established for:

- Pregnancy, unborn fetus, or delivery.
- Pediatric use (patients under the age of 16).
- Patients with neurological disease origins, such as multiple sclerosis or diabetes.
- Bilateral stimulation.

InterStim Therapy for bowel control

Indications

InterStim Therapy for bowel control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

Precautions

Clinician training

- **Implanting clinicians** should be trained on the implantation and use of the InterStim Neurostimulation System.
- **Prescribing clinicians** should be experienced in the diagnosis and treatment of fecal incontinence and should be trained on the use of the InterStim Neurostimulation System.

Use in specific populations

The safety and effectiveness of this therapy has not been established for:

- Pregnancy, unborn fetus, or delivery.
- Pediatric use (patients under the age of 16).
- Patients with progressive, systemic neurological diseases.
- Bilateral stimulation.

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InterStim II Model 3058 Neurostimulator

5. Fully insert the torque wrench into the self-sealing grommet of the connector block and tighten the setscrew by turning clockwise until the torque wrench clicks (Figure 4).

△ **Cautions:**

- Be sure the torque wrench is fully inserted into the self-sealing grommet. If the torque wrench is not fully inserted, the setscrew may be damaged, resulting in intermittent or loss of stimulation.
- Before tightening the setscrew, ensure that the lead is inserted into the connector block to prevent damaging the connector block.
- Verify that the self-sealing grommet is closed after the torque wrench is withdrawn. If fluid leaks through a grommet seal that is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant location, or intermittent stimulation or loss of stimulation may occur.
- Discard the torque wrench after making the connection. The torque wrench is single-use-only. Its operation cannot be assured if it is used for multiple surgeries.

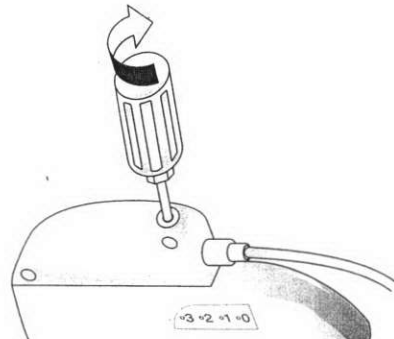


Figure 4. Tighten the setscrew in the self-sealing grommet by turning clockwise until the torque wrench clicks.

Note: The torque wrench must be oriented to the same angle as the setscrew (Figure 4).

InterStim II Model 3058 Neurostimulator

Implanting the Model 3058 Neurostimulator

1. Place the neurostimulator into the subcutaneous pocket with the etched identification side placed outward, away from muscle tissue, and ensure that the lead is not bent sharply.

Note: The Model 3058 Neurostimulator should be placed no deeper than 2.5 cm (1 in) below the skin and should be parallel to the skin. If the neurostimulator is too deep or is not parallel to the skin, telemetry may be unsuccessful.

Caution: Do not coil excess length in front of the etched identification side of the neurostimulator. Wrap excess length around the perimeter of the neurostimulator (Figure 5) to avoid increasing subcutaneous pocket depth, help minimize potential damage during neurostimulator replacement surgery, help minimize potential kinking, and minimize interference with telemetry during programming.

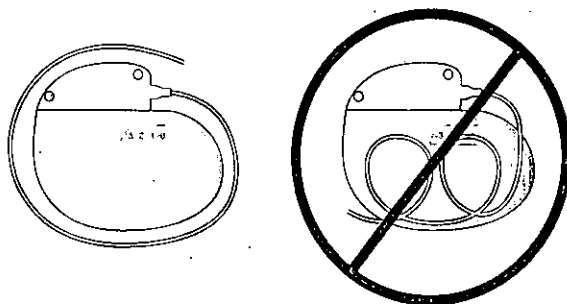


Figure 5. Wrap excess length around perimeter of the Model 3058 Neurostimulator.

2. Check the system integrity before securing the neurostimulator in place.
 - a. Use the clinician programmer and the product literature packaged with it to confirm the integrity of the connected system.

Caution: To use the nonsterile clinician programmer in a sterile field, place a sterile barrier between the patient and the programming head to prevent infection. Do not sterilize any part of the clinician programmer. Sterilization may damage the programmer.

Note: The neurostimulator should be in the pocket during system interrogation to ensure proper readings.

- b. Program the stimulation parameters you have selected for your patient according to the product literature packaged with the programmer.
- c. Check the battery status; if applicable, check the electrode impedances to rule out a short or open circuit.

InterStim II Model 3058 Neurostimulator

3. Use the two suture holes in the connector block to secure the neurostimulator to the muscle fascia with nonabsorbable silk.

Completing the implant procedure

1. Close and dress all incisions.
2. Ensure that a patient programmer and a patient ID card are given to the patient.

⚠ **Caution:** Because the patient programmer is the patient's only means to adjust or turn the neurostimulator on or off, the patient must carry a programmer at all times.

3. Complete the device tracking and patient registration paperwork and return the documents to Medtronic.

Note: See the Information for Prescribers booklet packaged with this device for clinician instructions to patients and for information regarding the return of product documentation.

4. Schedule regular patient follow-up appointments to monitor the condition of the neurostimulator and to confirm that the programmed parameter values are appropriate.

Replacing the Model 3058 Neurostimulator

If replacing a Model 3023 Neurostimulator, refer to page 26 of this manual.

1. Open the implant site using normal surgical procedure and carefully remove the neurostimulator from the subcutaneous pocket.
2. Clean the neurostimulator connector block and lead with sterile water; wipe dry with sterile gauze.
3. Insert a torque wrench through the prepierced hole in the rubber sealing grommet and loosen the setscrew by turning it counterclockwise.
4. Gently retract the lead from the neurostimulator connector block.

⚠ **Caution:** Replace any device that shows signs of damage, pitting, or corrosion.

5. Clean and dry the connector block and lead — which must be free of fluids or tissue.
6. Set aside the explanted components for return to Medtronic.
7. Connect the lead and replacement neurostimulator according to the product literature packaged with those devices.

Note: Increased pocket size may be necessary if replacement neurostimulator uses an extension.

8. Return explanted devices to Medtronic according to product literature packaged with those devices.

InterStim Model 3023 Neurostimulator

InterStim Model 3023 Neurostimulator

Device description

The Medtronic InterStim Model 3023 Neurostimulator is part of a neurostimulation system for InterStim Therapy.

Package contents

- Neurostimulator
- Torque wrench
- Product literature

Patient registration and identification card

The implant registration form registers the device and creates a record of the device in Medtronic's implant data system.

A patient identification card is packaged with this device. Advise the patient to carry the identification card at all times.

[USA] The patient identification card packaged with the device is temporary; a permanent card will be mailed to the patient when Medtronic receives the implant registration form.

Device specifications

The neurostimulator is a programmable device that accommodates an extension by which a stimulation program is delivered through a lead.

Refer to Table 4 for shipping, operating, and power-on-reset values. Refer to Table 5 for physical characteristics. Refer to Table 6 for materials of package components.

InterStim Model 3023 Neurostimulator

Table 4. Shipping, operating, and power-on-reset (POR) values for the InterStim Model 3023 Neurostimulator^a. Medtronic

Programmable Parameters	Shipping	Operating	POR ^b
Amplitude			
Normal Resolution	0.0 V	100 mV steps	0.0 V
Upper Limit	0.0 V	10.5 V maximum	0.0 V
Lower Limit	0.0 V	0.0 V minimum	0.0 V
Fine Resolution	---	50 mV steps	---
Upper Limit	---	6.35 V maximum	---
Lower Limit	---	0.0 V minimum	---
Rate	14 Hz	49 values (from 2.1 to 130 Hz)	31 Hz
Pulse Width	210 μ s	Increments of 30 μ s steps 450 μ s maximum 60 μ s minimum	210 μ s
Operating Mode	Continuous	Continuous or Cycling	Continuous
Cycle On/Cycle Off time^c	0.1 sec	0.1 sec to 24 hr	0.1 sec
SoftStart/Stop^d	Off	1, 2, 4, 8, 15, 30 sec, or Off	Off
Magnet Control	Disabled	Enabled/Disabled	Enabled
Output On/Off	Off	On or Off	Off
Polarity			
	Electrode Number	Polarity	
	0	—	—
	1	Off	Off
	2	Off	Off
	3	+	+
	Case ^e	Off	Off

^a All values are approximate.

^b Power-on-reset (POR) turns OFF stimulation by resetting the amplitude to 0.0 V and all electrodes to OFF. POR can occur when there is a temporary fluctuation in battery voltage (eg, due to electromagnetic interference during electrocautery or defibrillation) or the battery is depleted. When POR occurs, the serial number is reset to a nominal value and must be entered with the clinician programmer.

^c Cycle On and Cycle Off time must be greater than or equal to the SoftStart/Stop time.

^d SoftStart/Stop must be less than or equal to the Cycle On and Cycle Off time.

^e If case electrode is positive, electrodes 0-3 may be programmed to Off or — only.

InterStim Model 3023 Neurostimulator

Table 5. Physical characteristics of the InterStim Model 3023 Neurostimulator^a.

Description	Value
Height	55 mm (2.2 in)
Length	60 mm (2.4 in)
Thickness	10 mm (0.4 in)
Weight	42 g (1.5 oz)
Volume	22 cm ³ (1.3 in ³)
External shield	Titanium
Power source ^b	2.7 Amp hours, 3.7 V Lithium-thionyl chloride cell
Storage temperature	-18 °C to 52 °C (-0 °F to 125 °F)
Serial Number ^c	
Radiopaque Identification (ID)	NBV

^a All measurements are approximate.

^b The power source is hermetically sealed within the case.

^c The serial number is the radiopaque ID followed by a number. The clinician programmer displays the entire number beginning with the radiopaque ID.

InterStim Model 3023 Neurostimulator

X-Ray identification

Radiopaque identification permits the determination of manufacturer and neurostimulator model number (Figure 6). With standard x-ray procedures, the code appears as black characters on white background. The Medtronic symbol identifies Medtronic as the manufacturer. For the InterStim Model 3023 Neurostimulator, the designated characters are NBV.

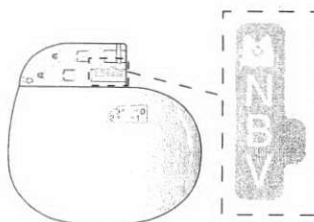


Figure 6. The InterStim Model 3023 Neurostimulator radiopaque code block.

Table 6. Material of components in the Model 3023 package.

Structure	Material	Material Contacts Human Tissue
Case ^a	Titanium	Yes
Connector	Urethane	Yes
Grommets, seals	Silicone rubber	Yes
Setscrews	Titanium	Yes
Insulation coating ^b	Polymeric insulating film	Yes
Adhesive	Silicone adhesive	Yes
Torque wrench		
Handle	Polyetherimide	Yes
Shaft	Stainless steel	Yes

^a The electronics and power source are hermetically sealed within the case.

^b The etched side of the Model 3023 case is uninsulated and can be programmed as an indifferent electrode.

InterStim Model 3023 Neurostimulator.

Instructions for use: Model 3023

△ Cautions:

- When using sharp instruments near the neurostimulator, be careful to avoid nicking, or damaging the case, the insulation, or the connector block. Damaging the neurostimulator may require surgical replacement.
- Do not use saline or other ionic fluids at connections, which could result in a short circuit.

Verifying neurostimulator operation

Before opening the sterile neurostimulator package, use the clinician programmer to interrogate the neurostimulator and verify neurostimulator battery status and current settings.

- △ **Caution:** Do not implant a neurostimulator if it was dropped onto a hard surface from a height of 30 cm (12 in) or more, because the neurostimulator may be damaged and fail to operate properly.

Creating a pocket for the Model 3023 Neurostimulator

1. Create a subcutaneous pocket for the neurostimulator by blunt dissection to the anterior surface of the muscle. The neurostimulator is typically placed in the upper buttock area.

Notes:

- Abdominal placement is an option with the Model 3023 Neurostimulator. Abdominal implant instructions are included in the product literature packaged with the leads.
- The Model 3023 Neurostimulator should be placed no deeper than 4 cm (1.5 in) below the skin and should be parallel to the skin. If the neurostimulator is too deep or is not parallel to the skin, telemetry may be unsuccessful.
- The uncoated, etched side of the 3023 case can be programmed as an indifferent electrode. The etched side of the neurostimulator must face away from muscle to prevent uncomfortable stimulation.
- If the patient has any other neurostimulator, the neurostimulators must be separated by a minimum 20 cm (8 in).
- The Model 3023 Neurostimulator requires the use of an extension.

△ Cautions:

- The neurostimulator is provided sterile. Do not soak the neurostimulator in antibiotic solution. Soaking in antibiotic solution can affect lead connections.
- To avoid infection, it is recommended that the neurostimulator implant site be irrigated with antibiotic solution, and that IV antibiotics be administered perioperatively. Do not allow the neurostimulator to come into contact with any non-sterile surface. Do not place on skin. If an infection occurs, it may require surgical removal of the implanted system.

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InterStim Model 3023 Neurostimulator

2. Place the neurostimulator in the pocket to assure proper fit and then remove it. Keep the neurostimulator sterile and clean.
3. Tunnel from the lead incision site to the neurostimulator pocket. Refer to the product literature packaged with the lead for detailed tunneling and lead implant instructions.
4. Wipe the proximal end of the lead with sterile gauze and make sure the extension is dry and clean.
5. Connect and implant the lead and extension according to product literature packaged with those devices.
6. Connect the extension to the Model 3023 Neurostimulator according to the steps in "Connecting the extension to the Model 3023 Neurostimulator" in this manual.

Connecting the extension to the Model 3023 Neurostimulator

△ **Caution:** Before connecting components, wipe off any body fluids and dry all connections. Fluids in the connection may result in stimulation at the connection site, intermittent stimulation, or loss of stimulation.

1. Wipe the extension connector pins with sterile gauze. If necessary, use sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution, then wipe dry.
2. Make sure the connector block receptacles are dry and clean.
3. Confirm that the encapsulated diagram on the extension has four electrodes matching the encapsulated diagram on the neurostimulator (Figure 7).
4. Insert the extension connector pins into the neurostimulator until they are fully seated within the connector block (Figure 7).

△ **Caution:** Do not pull the extension or lead body taut when implanted. The extension and lead are available in different lengths. Select a length that allows connection without tension.

Note: To retract the setscrews, insert the torque wrench into the self-sealing grommet and rotate the setscrews counterclockwise; however, do not remove the setscrews from the connector block (Figure 8):

△ **Caution:** Do not insert the extension connector pins into the connector block if the setscrews are not sufficiently retracted. If the setscrews are not retracted, the extension connector pins may damage the setscrews and the extension connector pins will not be seated fully into the connector block.

InterStim Model 3023 Neurostimulator

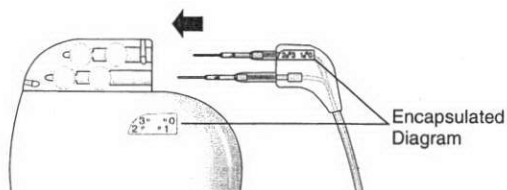


Figure 7. Insert extension connector pins fully into Model 3023 Neurostimulator connector block.

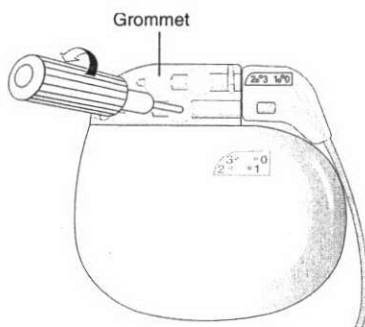


Figure 8. To back out a setscrew from the Model 3023 Neurostimulator, use the torque wrench and turn the setscrew counterclockwise.

Note: The torque wrench must be oriented to the same angle as the setscrew (Figure 8).

InterStim Model 3023 Neurostimulator

5. Fully insert the torque wrench into the self-sealing grommet of the connector block and tighten each setscrew by turning clockwise until the torque wrench clicks (Figure 9).

△ **Cautions:**

- Be sure the torque wrench is fully inserted into the self-sealing grommet. If the torque wrench is not fully inserted, the setscrew may be damaged, resulting in intermittent or loss of stimulation.
- Before tightening setscrews, ensure that the extension connector pins are inserted into the connector block to prevent damaging the connector block.
- Verify that each self-sealing grommet is closed after the torque wrench is withdrawn. If fluid leaks through a grommet seal that is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant location, or intermittent stimulation or loss of stimulation may occur.
- Discard the torque wrench after making all of the connections. The torque wrench is single-use-only. Its operation cannot be assured if it is used for multiple surgeries.

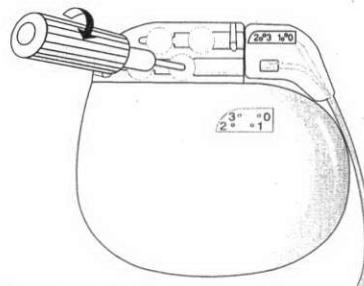


Figure 9. Tighten the setscrews in the self-sealing grommet by turning clockwise until the torque wrench clicks.

Note: The torque wrench must be oriented to the same angle as the setscrew (Figure 9).

InterStim Model 3023 Neurostimulator

Implanting the Model 3023 Neurostimulator

1. Place the neurostimulator into the subcutaneous pocket with the etched identification side placed outward, away from muscle tissue, and ensure that the extension is not bent sharply.

Note: The Model 3023 Neurostimulator should be placed no deeper than 4 cm (1.5 in) below the skin and should be parallel to the skin. If the neurostimulator is too deep or is not parallel to the skin, telemetry may be unsuccessful

△ Cautions:

- Do not place the etched identification side of the neurostimulator facing inward. Placing the etched side inward could increase the possibility of skeletomuscular stimulation, which the patient may perceive as twitching or burning.
- Do not coil excess length in front of the etched identification side of the neurostimulator. Wrap excess length around the perimeter of the neurostimulator (Figure 10) to avoid increasing subcutaneous pocket depth, help minimize potential damage during neurostimulator replacement surgery, help minimize potential kinking, and minimize interference with telemetry during programming.

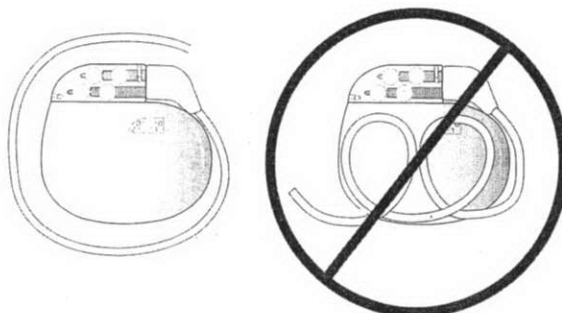


Figure 10. Wrap excess extension around the perimeter of the Model 3023 Neurostimulator.

2. Check the system integrity before securing the neurostimulator in place.
 - a. Use the clinician programmer and the product literature packaged with it to confirm the integrity of the connected system.

InterStim Model 3023 Neurostimulator

△ **Caution:** To use the nonsterile clinician programmer in a sterile field, place a sterile barrier between the patient and the programming head to prevent infection. Do not sterilize any part of the clinician programmer. Sterilization may damage the programmer.

Note: The neurostimulator should be in the pocket during system interrogation to ensure proper readings.

- b. Program the stimulation parameters you have selected for your patient according to product literature packaged with the programmer.
- c. Check the battery status; if applicable, check the electrode impedances to rule out a short or open circuit.
3. Use the two suture holes in the connector block to secure the neurostimulator to the muscle fascia with nonabsorbable silk.

Completing the implant procedure

1. Close and dress all incisions.
2. Ensure that a patient programmer and a patient ID card are given to the patient.

△ **Caution:** Because the patient programmer is used to adjust or turn the neurostimulator on or off, the patient must carry a programmer at all times. Patients implanted with a Model 3023 Neurostimulator may also receive the optional Model 7452 Control Magnet that is used to turn the neurostimulator on or off. In order for the control magnet to turn the neurostimulator on or off, the clinician must enable Magnet Control on the Model 3023 Neurostimulator using the clinician programmer. Magnet Control can not be enabled or disabled using the patient programmer.

3. Complete the device tracking and patient registration paperwork and return the documents to Medtronic.

Note: See the Information for Prescribers booklet packaged with this device for clinician instructions to patients and for information regarding the return of product documentation.


4. Schedule regular patient follow-up appointments to monitor the condition of the neurostimulator and to confirm that the programmed parameter values are appropriate.

Replacing the Model 3023 Neurostimulator

If replacing a Model 3058 Neurostimulator, refer to page 16 of this manual.

1. Open the implant site using normal surgical procedure and carefully remove the neurostimulator from the subcutaneous pocket.
2. Clean the neurostimulator connector block and extension connector with sterile water; wipe lead dry with surgical sponges.
3. Insert a torque wrench through each prepierced hole in the rubber seating grommet and loosen the setscrews by turning them counterclockwise.
4. Gently retract the extension connector pins from the neurostimulator connector block.

InterStim Model 3023 Neurostimulator

 **Caution:** Replace any device that shows signs of damage, pitting, or corrosion.

5. Clean and dry the connector block and extension connector pins which must be free of fluids or tissue.

Note: If the replacement neurostimulator does not require the existing extension, disconnect the extension from the lead. Clean and dry the proximal end of the lead. Take care not to move the lead when extension is disconnected.

6. Set aside the explanted components for return to Medtronic.
7. Connect the replacement neurostimulator according to the product literature packaged with that device.
8. Return explanted devices to Medtronic according to product literature packaged with those devices.

Declaration of conformity

Medtronic declares that the Model 3058 and Model 3023 Neurostimulators are in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment and Directive 90/385/EEC on Active Implantable Medical Devices.

For additional information, contact the appropriate Medtronic office listed on the inside back cover of this manual.

InterStim Model 3023 Neurostimulator

Control magnet

The Medtronic Model 7452 Control Magnet allows your patient to turn the Model 3023 Neurostimulator on or off. The control magnet is not used with the Model 3058 Neurostimulator. When the control magnet on/off control circuit is enabled, applying the flat, rectangular edge of the control magnet over the implant site for 1 to 2 seconds (Figure 11) and then removing it turns the neurostimulator on or off.

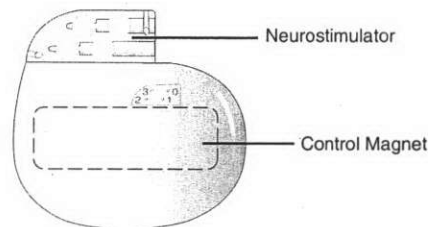


Figure 11. Control magnet properly positioned over the Model 3023 Neurostimulator.

If SoftStart/Stop is in use, turning the Model 3023 Neurostimulator on causes the amplitude to ramp up from zero to the selected output amplitude. Turning the neurostimulator off causes the amplitude to ramp down to zero again. The ramp time is set by the SoftStart/Stop parameters. The control magnet on/off control circuit does not affect programmed parameters; when the output is turned on with the control magnet, the output resumes its previously programmed waveform and stimulation mode.

For patients who live or work in electrically noisy environments, random on or off switching may be a problem. If on or off switching occurs, you can disable the magnet control circuitry with a command to the neurostimulator from the clinician programmer. Detailed instructions on disabling this feature are provided in the product literature packaged with the programmer software.

Note: The patient with a Model 3023 Neurostimulator may carry the optional control magnet to turn the neurostimulator on or off.

The patient programmer will still operate the neurostimulator because it uses a different circuit than the control magnet to turn the neurostimulator on or off. The magnet control circuit can be enabled again with another command from the clinician programmer, if desired.

Caution: Because the patient programmer is used to adjust or turn on or off the neurostimulator, the patient must carry a programmer at all times. Patients implanted with a Model 3023 Neurostimulator may also receive the optional Model 7452 Control Magnet that is used to turn the neurostimulator on or off. In order for the control magnet to turn the neurostimulator on or off, the clinician must enable Magnet Control on the Model 3023 Neurostimulator using the clinician programmer. Magnet Control can not be enabled or disabled using the patient programmer.

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Bowel Control Clinical Trial Results

The Medtronic InterStim system was evaluated in a prospective multicenter trial at study centers in the United States, Canada, and Australia for the indication of chronic fecal incontinence.

Study Design and Methods

Trial Eligibility

The main study inclusion criteria were:

- 18 years of age or older
- Diagnosis of chronic fecal incontinence of duration greater than six months (>12 months post-vaginal childbirth) and defined as >2 incontinent episodes on average per week of more than staining recorded during the baseline diary period
- Failing or not being a candidate for more conservative treatments (such as diet modification, medical management, or biofeedback therapy)

The main study exclusion criteria were:

- Congenital anorectal malformations
- Present rectal prolapse
- Previous rectal surgery (such as rectopexy or resection) or sphincteroplasty done less than 12 months prior to study enrollment (24 months for cancer)
- Neurological diseases such as clinically significant peripheral neuropathy or complete spinal cord injury (i.e., paraplegia)
- Grade III hemorrhoids
- Known or suspected organic disorders of the bowel (i.e., inflammatory bowel disease such as Crohn's or ulcerative colitis)
- Chronic watery diarrhea, unmanageable by drugs or diet, as primary cause of fecal incontinence. (Incontinent episodes with a Bristol stool consistency of ≥ 6 for ≥ 4 days during the baseline diary period will be exclusionary, unless the investigator determined that the diary was not indicative of chronic watery diarrhea)
- Pregnant or planned pregnancy
- History of pelvic irradiation who presented with visible or functional effects of irradiation
- Active anal abscesses or fistulas
- Anatomical limitations that would have prevented the successful placement of an electrode
- Knowledge of planned MRIs, diathermy, microwave, or RF energy
- Defect of external anal sphincter of > 60 degrees or amenable to surgical repair

Design - The clinical study was a prospective, multicenter, non-randomized trial to determine the safety and effectiveness of sacral nerve stimulation for the treatment of chronic fecal incontinence. Patients who had motor and/or sensory response to an acute needle test (e.g., pulling sensation in the rectum, extending forward to the scrotum or labia, bellows response, clamp of anal sphincter, leg/hip rotation, plantar flexion of the entire foot) and who had a successful test stimulation (at-home evaluation during which only symptom responses were recorded) were eligible for permanent implant of the InterStim system.

Implanted patients were to be followed for a minimum of 12 months post-implant to demonstrate the safety and effectiveness of the InterStim Therapy.

Methods - The effect of InterStim Therapy on fecal incontinence was evaluated using a bowel diary as the primary outcome measure. To qualify for test stimulation, patients were required to complete a baseline Medtronic bowel diary to demonstrate greater than two incontinent episodes on average per week of more than staining. Bowel diary results completed during the test stimulation period were compared to those completed at baseline. Patients must have shown at least a 50% improvement during test stimulation compared to baseline to qualify for implantation of the InterStim system.

Treatment response was assessed on the basis of a Medtronic bowel diary for a minimum of 10 consecutive 24 hour periods, not to exceed 14 days. In order for the patient to qualify for permanent implant, the following success criteria were required to be met during the test stimulation phase.

- $\geq 50\%$ reduction in number of incontinence episodes/week
and/or
- $\geq 50\%$ reduction in number of incontinence days/week

When compared to the baseline diary.

Follow-up visits for all implanted patients were scheduled at 3 months, 6 months and 12 months and then annually. The Medtronic bowel diary (including a question regarding pad use) was completed two weeks prior to the scheduled follow-up visit. The Fecal Incontinence Quality of Life (FIQOL)¹, Fecal Incontinence Severity Index (FISI)², self-rated bowel health questions (overall perception of bowel health), and anal manometry (maximal mean incremental squeeze pressure, and maximal mean resting pressure) were completed during each follow-up visit.

¹ Rockwood TH, Church JM, Fleshman JW, et al. Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. *Dis Colon Rectum*. Jan 2000;43(1):9-16; discussion 116-17.

² Rockwood TH, Church JM, Fleshman JW, et al. Patient and surgeon ranking of the severity of symptoms associated with fecal incontinence: the fecal incontinence severity index. *Dis Colon Rectum*. Dec 1999;42(12):1525-1532.

The bowel diary was a measurement tool developed by Medtronic and its investigators for use by subjects to record information about their bowel episodes. Over the diary period, subjects recorded the date and time of each bowel episode and responded to the following 5 questions related to each bowel episode:

- Amount of incontinence: *none, staining, minor soiling, major soiling*
- Urgency: *no, yes*
- Ability to defer defecation: *"How long were you able to hold your bowel movement"*
- Stool description (Bristol Stool Scale): *1-7*
- Nocturnal bowel habits: *"Did the episode occur while you were sleeping or wake you from sleep"*

A bowel movement was considered *incontinent* if the amount of incontinence was *minor soiling* or *major soiling*.

Primary Endpoints Included:

Safety – characterization of adverse events experienced with the use of the InterStim Therapy System in patients with fecal incontinence during both the test stimulation and permanent implantation.

Effectiveness – demonstrate that at least 50% of subjects will achieve at least a 50% reduction in the number of incontinent episodes per week at 12 months post implantation compared to baseline.

Secondary Endpoints Included:

- Demonstrate that at least 50% of subjects will achieve at least 50% reduction in the number of incontinent days per week at 12 months post implant compared to baseline.
- Demonstrate improvement in Fecal Incontinence Quality of Life (FIQOL) scores at 12 months post-implant compared to baseline. The four component scales of the FIQOL instrument will be analyzed separately.
 - Scale 1 – lifestyle
 - Scale 2 – Coping/Behavior
 - Scale 3 – Depression/Self-Perception
 - Scale 4 – Embarrassment

- Demonstrate that at least 50% of subjects will achieve at least 50% reduction to the number of urgent incontinent episodes per week at 12 months compared to baseline.

An intent-to-treat analysis was conducted which assumed no change for patients who were missing bowel diaries at the 12-month visit unless a subsequent bowel diary was available (modified worst-case analysis). Another per-protocol analysis was conducted for patients who had complete data both at baseline and at the 12-month visit (completers analysis)

Study Results

Two hundred eighty-five (285) patients were enrolled in the study. Of these 285 enrolled patients, 132 met inclusion/exclusion criteria and underwent at least one, and in some cases, up to two test stimulation procedures using a staged implant technique. Of these 132 patients who underwent test stimulation, 120 patients (91%) had a successful test stimulation result and were implanted with the InterStim System. The average post-implant follow-up duration was 28 months (ranging from 2.2 to 69.5 months). The effectiveness of the device was evaluated for all trial subjects at 12 months. In addition, adverse event data was collected from subjects who had the device implanted for 12 months (N=111), 24 months (N=76), 36 months (N=34), 48 months (N=14), and 60 months (N=3).

Baseline Demographics

The mean age of the 120 implanted patients was 60.5 years (range 30.4 to 88 years) and 92% were women. The most common etiology of fecal incontinence was obstetric trauma (46%). The type of fecal incontinence was passive (no awareness of loss of stool) in 45% of patients, urge (inability to defer defecation) in 41%, and both urge and passive in 14%. The mean duration of fecal incontinence since diagnosis was 6.8 years (median 3.5, range 1 to 44). As shown in Table 1, the patients experienced significant fecal incontinence symptoms at baseline, reporting an average number of 9.4 incontinent episodes per week (median 6.8) and an average number of 4.5 incontinent days per week (median 4.4).

Table 1: Baseline Fecal Incontinence Symptoms

Symptom	N	Mean	Std Dev	Minimum	Median	Maximum
Weekly Incontinent Episodes	120	9.4	7.3	2.3	6.8	42.0
Weekly Incontinent Days	120	4.5	1.6	1.0	4.4	7.0
Weekly Urgent	120	4.9	4.9	0.0	3.3	26.7

Symptom	N	Mean	Std Dev	Minimum	Median	Maximum
Incontinent Episodes						

The occurrence of double (fecal and urinary) incontinence was a common finding in this study. Many of the patients reported urinary voiding disorders such as urinary urge incontinence (33%), urinary stress incontinence (16%), urinary urgency frequency (10%), and urinary retention (6%).

Thirty-four patients (28%) reported that they had previously undergone anal sphincteroplasty that had failed to correct the fecal incontinence. Other prior surgical pelvic procedures included hysterectomy (55%), cystocele repair (14%), rectocele repair (13%), pelvic floor repair (7%), uterine prolapse repair (5%), enterocele repair (3%).

Adverse Events

Staged implant test stimulation

A total of 132 patients had a staged implant test stimulation procedure. As shown in Table 2, there were 35 adverse events related to the device or use of the therapy reported in 23 (17.4%) patients during the test stimulation phase.

Table 2: Device or Therapy Related Adverse Events During Test Stimulation

Adverse Event Preferred Term	Number of Events	Number (%) of Patients (n=132)
Implant site pain	5	5(3.8%)
Lead fracture	3	2(1.5%)
Hematoma	2	2(1.5%)
Lead migration/dislodgment	2	2(1.5%)
Pain in extremity	2	2(1.5%)
Skin irritation	2	2(1.5%)
Buttock pain	1	1(0.8%)
Chest pain	1	1(0.8%)
Constipation	1	1(0.8%)
Device malfunction	1	1(0.8%)
Diarrhea	1	1(0.8%)

Adverse Event Preferred Term	Number of Events	Number (%) of Patients (n=132)
Discomfort	1	1(0.8%)
Ecchymosis	1	1(0.8%)
Extension fracture	1	1(0.8%)
Hemorrhage	1	1(0.8%)
Implant site effusion	1	1(0.8%)
Implant site infection	1	1(0.8%)
Incisional drainage	1	1(0.8%)
Nausea	1	1(0.8%)
Pain	1	1(0.8%)
Paraesthesia	1	1(0.8%)
Urinary incontinence	1	1(0.8%)
Urinary retention	1	1(0.8%)
Urinary tract infection	1	1(0.8%)
Vaginal pain	1	1(0.8%)
Total	35	23(17.4%)

Note: the total number of patients may not add down columns, as the same patient may have experienced more than one type of event.

Post-neurostimulator implant

A total of 120 patients had the neurostimulator implanted following successful staged implant test stimulation. As shown in Table 3, there were 237 adverse events related to the device or use of the therapy reported in 88 (73.3%) patients during the implant phase. The reported adverse event rate is cumulative through the duration of the study (average post-implant follow-up duration was 28 months, ranging from 2.2 to 69.5 months). The majority of these adverse events resolved spontaneously, with re-programming, or with medications.

Table 3: Device or Therapy Related Adverse Events Post Implant

Adverse Events Preferred Term	Number of Events (Cumulative)	Number (%) of Patients (Cumulative) (n=120)	Number of Events (Number of Patients) (≤ 1 year)	Number of Events (Number of Patients) (1 - 2 years)	Number of Events (Number of Patients) (> 2 years)
Implant site pain	37	31(25.8%)	29(25)	7(7)	1(1)
Paraesthesia	19	15(12.5%)	12(11)	5(5)	2(2)
Implant site infection	14	13(10.8%)	10(9)	3(3)	1(1)
Change in sensation of stimulation	12	10(8.3%)	8(6)	0(0)	4(4)
Urinary incontinence	8	8(6.7%)	7(7)	0(0)	1(1)
Diarrhea	6	6(5.0%)	5(5)	1(1)	0(0)
Constipation	5	5(4.2%)	5(5)	0(0)	0(0)
Neurostimulator programming error	5	5(4.2%)	5(5)	0(0)	0(0)
Pain	5	5(4.2%)	3(3)	0(0)	2(2)
Pain in extremity	5	5(4.2%)	5(5)	0(0)	0(0)
Urinary tract infection	5	5(4.2%)	3(3)	2(2)	0(0)
Back pain	4	4(3.3%)	4(4)	0(0)	0(0)
Buttock pain	4	4(3.3%)	4(4)	0(0)	0(0)
Proctalgia	4	4(3.3%)	3(3)	1(1)	0(0)
Seroma	4	4(3.3%)	4(4)	0(0)	0(0)
Urinary retention	4	4(3.3%)	3(3)	0(0)	1(1)
Lead migration/dislodgment	5	3(2.5%)	2(1)	1(1)	2(2)
Coccydynia	3	3(2.5%)	1(1)	1(1)	1(1)
Defaecation urgency	3	3(2.5%)	2(2)	0(0)	1(1)
Implant site erosion	3	3(2.5%)	3(3)	0(0)	0(0)
Incontinence	3	3(2.5%)	3(3)	0(0)	0(0)
Neurostimulator battery depletion	3	3(2.5%)	0(0)	2(2)	1(1)
Skin irritation	3	3(2.5%)	3(3)	0(0)	0(0)

Adverse Events Preferred Term	Number of Events (Cumulative)	Number (%) of Patients (Cumulative) (n=120)	Number of Events (Number of Patients) (≤ 1 year)	Number of Events (Number of Patients) (1 - 2 years)	Number of Events (Number of Patients) (> 2 years)
Therapeutic product ineffective	3	3(2.5%)	3(3)	0(0)	0(0)
Urinary tract disorder	3	3(2.5%)	3(3)	0(0)	0(0)
Unclassified (pain/tingling, pain)	2	2(1.7%)	0(0)	0(0)	2(2)
Cystitis	2	2(1.7%)	1(1)	1(1)	0(0)
Erythema	2	2(1.7%)	1(1)	0(0)	1(1)
Lead fracture	2	2(1.7%)	2(2)	0(0)	0(0)
Micturition urgency	2	2(1.7%)	2(2)	0(0)	0(0)
Muscle spasms	2	2(1.7%)	2(2)	0(0)	0(0)
Neurostimulator migration	2	2(1.7%)	1(1)	1(1)	0(0)
Pelvic pain	2	2(1.7%)	1(1)	1(1)	0(0)
Pollakiuria	2	2(1.7%)	1(1)	1(1)	0(0)
Wound dehiscence	2	2(1.7%)	2(2)	0(0)	0(0)
High impedance	2	1(0.8%)	1(1)	0(0)	1(1)
Scrotal pain	2	1(0.8%)	2(1)	0(0)	0(0)
Abdominal pain	1	1(0.8%)	1(1)	0(0)	0(0)
Abnormal faeces	1	1(0.8%)	0(0)	1(1)	0(0)
Anal discomfort	1	1(0.8%)	1(1)	0(0)	0(0)
Anorectal disorder	1	1(0.8%)	1(1)	0(0)	0(0)
Arthralgia	1	1(0.8%)	1(1)	0(0)	0(0)
Bursitis	1	1(0.8%)	1(1)	0(0)	0(0)
Chest pain	1	1(0.8%)	1(1)	0(0)	0(0)
Depression	1	1(0.8%)	1(1)	0(0)	0(0)
Dermatitis	1	1(0.8%)	1(1)	0(0)	0(0)
Device malfunction	1	1(0.8%)	1(1)	0(0)	0(0)
Ecchymosis	1	1(0.8%)	1(1)	0(0)	0(0)
Extension fracture	1	1(0.8%)	1(1)	0(0)	0(0)

Adverse Events Preferred Term	Number of Events (Cumulative)	Number (%) of Patients (Cumulative) (n=120)	Number of Events (Number of Patients) (≤ 1 year)	Number of Events (Number of Patients) (1 - 2 years)	Number of Events (Number of Patients) (> 2 years)
Faecaloma	1	1(0.8%)	1(1)	0(0)	0(0)
Flatulence	1	1(0.8%)	1(1)	0(0)	0(0)
Frequent bowel movements	1	1(0.8%)	1(1)	0(0)	0(0)
Gastrointestinal disorder	1	1(0.8%)	0(0)	1(1)	0(0)
Gastrointestinal motility disorder	1	1(0.8%)	0(0)	1(1)	0(0)
Genital pruritus female	1	1(0.8%)	1(1)	0(0)	0(0)
Haematoma	1	1(0.8%)	1(1)	0(0)	0(0)
Headache	1	1(0.8%)	0(0)	1(1)	0(0)
Hypoaesthesia	1	1(0.8%)	0(0)	1(1)	0(0)
Implant site discharge	1	1(0.8%)	1(1)	0(0)	0(0)
Implant site effusion	1	1(0.8%)	1(1)	0(0)	0(0)
Implant site erythema	1	1(0.8%)	1(1)	0(0)	0(0)
Implant site irritation	1	1(0.8%)	0(0)	1(1)	0(0)
Implant site swelling	1	1(0.8%)	1(1)	0(0)	0(0)
Incision site complication	1	1(0.8%)	1(1)	0(0)	0(0)
Insomnia	1	1(0.8%)	1(1)	0(0)	0(0)
Nausea	1	1(0.8%)	1(1)	0(0)	0(0)
Pyrexia	1	1(0.8%)	1(1)	0(0)	0(0)
Rash	1	1(0.8%)	1(1)	0(0)	0(0)
Rectal discharge	1	1(0.8%)	1(1)	0(0)	0(0)
Sacral pain	1	1(0.8%)	1(1)	0(0)	0(0)
Sciatica	1	1(0.8%)	1(1)	0(0)	0(0)
Sensation of heaviness	1	1(0.8%)	1(1)	0(0)	0(0)
Sensory disturbance	1	1(0.8%)	0(0)	0(0)	1(1)
Tenderness	1	1(0.8%)	1(1)	0(0)	0(0)

Adverse Events Preferred Term	Number of Events (Cumulative)	Number (%) of Patients (Cumulative) (n=120)	Number of Events (Number of Patients) (≤ 1 year)	Number of Events (Number of Patients) (1 - 2 years)	Number of Events (Number of Patients) (> 2 years)
Toe deformity	1	1(0.8%)	1(1)	0(0)	0(0)
Vaginal pain	1	1(0.8%)	1(1)	0(0)	0(0)
Vomiting	1	1(0.8%)	1(1)	0(0)	0(0)
Vulvovaginal discomfort	1	1(0.8%)	1(1)	0(0)	0(0)
Wound	1	1(0.8%)	1(1)	0(0)	0(0)
Wound complication	1	1(0.8%)	1(1)	0(0)	0(0)
Total	237	88(73.3%)	182(78)	33(26)	22(17)

Note: the total number of patients may not add across rows, as the same patient may have experienced the same type of event more than once; similarly the total number of patients may not add down columns, as the same patient may have experienced more than one type of event.

Serious Adverse Events

Device or therapy related serious adverse events that occurred post implant are provided in Table 4.

Table 4: Device or Therapy Related Serious Adverse Events Post-Implant

Adverse Event Preferred Term	Number of Serious Events	Number (%) of Patients (n=120)
Implant site infection	6	5 (4.2%)
Implant site pain	4	3 (2.5%)
Seroma	3	3 (2.5%)
Implant site erosion	2	2 (1.7%)
Defecation urgency	1	1 (0.8%)
Lead migration/dislodgment	1	1 (0.8%)
Therapeutic product ineffective	1	1 (0.8%)
Urinary retention	1	1 (0.8%)
Urinary tract infection	1	1 (0.8%)
Total	20	13 (10.8%)

Note: the total number of patients may not add down columns, as the same patient may have experienced more than one type of event.

There were no device/therapy-related deaths in the study; there were three patient-related deaths.

Surgical Revisions

Out of 120 patients implanted with the InterStim system, 22 had at least one revision or replacement. The cumulative probability of the patient needing surgical revision (including device replacement) was 10% at 12 months and 17% at 24 months.

Fourteen patients had their InterStim systems explanted. Six were explanted due to lack of efficacy, two for skin erosion, two for implant site infection, one for recurrent seroma, one for implant site pain, one for untreatable diarrhea, and one was explanted to undergo an MRI secondary to an adrenal mass.

Effectiveness

Bowel diary results showed significant reduction in fecal incontinence in patients implanted with the InterStim system at 12 months compared to baseline. Table 4 shows success rates at 12-months post implant. With conservative assumptions (no change from baseline) for patients lost to follow-up or with missing diary data at twelve months post implant (modified worst-case analysis), 73% of patients had achieved at least 50% reduction in incontinent episodes per week. With per-protocol analysis where only patients with complete data at baseline and at 12-months were evaluated, 83% of patients had achieved at least 50% reduction in incontinent episodes per week.

Table 4: Success Rates at 12-Months Post Implant

Effectiveness Outcome	Intent-to-Treat (Modified Worst-Case) Analysis (n=120)	Per-Protocol (Completers) Analysis (n=106)
≥50% reduction in incontinent episodes per week from baseline	73% (88/120)	83% (88/106)
≥50% reduction in incontinent days per week from baseline	73% (88/120)	83% (88/106)
≥50% reduction in urgent incontinent episodes per week from baseline	71% (85/120)	80% (85/106)

Table 5 shows the average number of incontinent episodes per week, the average incontinent days per week, and the average urgent incontinent episodes per week as reported by patients at baseline and at 12-months post implant.

Table 5 Fecal Incontinence Symptoms at Baseline and 12-Months Post Implant

	Intent-to-Treat (Modified Worst-Case) Analysis (n=120)		Per Protocol (Completers) Analysis (n=106)	
Fecal Incontinence Symptoms	Baseline	12-Months	Baseline	12-Months
Average incontinent episodes per week	9.4	3.1	9.2	1.9
Average incontinent days per week	4.5	1.5	4.5	1.1
Average urgent incontinent episodes per week	5.0	1.7	4.9	1.2

Table 6 shows categorized percent improvement in incontinent episodes per week from baseline to 12-months post implant. With the intent-to-treat (modified worst-case) analysis, 35.8% of patients achieved full continence of bowel movements, and with the per protocol (completers) analysis, 40.6% achieved full continence.

Table 6 Improvement Categories (Incontinent Episodes Per Week).

	Intent-to-Treat (Modified Worst-Case) Analysis (n=120)		Per Protocol (Completers) Analysis (n=106)	
Improvement Categories (Incontinent Episodes Per Week)	Number of Subjects	Percent of Subjects	Number of Subjects	Percent of Subjects
100%	43	35.8%	43	40.6%
75-99%	30	25.0%	30	28.3%
50-74%	15	12.5%	15	14.2%
1-49%	10	8.3%	10	9.4%
≤ 0%	22*	18.3%	8	7.6%

*This includes 14 subjects who did not complete the 12 month bowel diary; therefore, their baseline bowel diary was used as their 12 month bowel diary and thus did not show a decrease in bowel episodes per week.

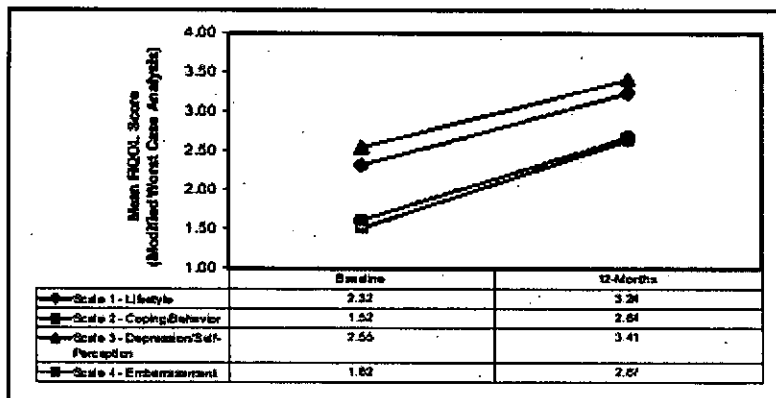
Internal Anal Sphincter (IAS) Defect

The presence of an Internal Anal Sphincter (IAS) defect often implies that an obstetric tear has extended through the external anal sphincter (EAS) to involve the IAS. A disruption of the IAS may indicate a more severe injury. Based on a per-protocol (completers) analysis, the success rate among 20 patients with an IAS defect was 65%, compared to 87% among the 86 patients without an IAS defect. This suggests that the presence of an IAS defect may be associated with reduced success; nonetheless, more than half of the patients (65%) with severe sphincter defect were still able to demonstrate effectiveness with the InterStim system.

Improvement in Quality of Life

Patients implanted with the InterStim system reported improvements in various aspects of their quality of life. To evaluate these improvements, patients completed questionnaires that measured their quality of life, perception of bowel health, and severity of their fecal incontinence. As shown in Figure 1, patients reported significant improvement in their quality of life at 12 months. This included lifestyle, coping/behavior, depression/self-perception, and embarrassment. Patient perception of their bowel health, on average, doubled from baseline to a more favorable state at 12 months. Additionally, the leakage of gas, mucus, liquid and solid stool showed a significant decrease at 12 months. Use of minipads/panty liners and other forms of protective undergarment was significantly reduced during the follow-up period.

Figure 1. Twelve Months Fecal Incontinence Quality of Life Results (n=120)



Anorectal manometry was performed at baseline and each post implant follow-up to assess maximal mean resting pressure and maximal mean incremental squeeze pressure. Significant improvement in fecal incontinence symptoms were observed without improvement in these specific anal manometry parameters.

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YOUR INTERSTIM® THERAPY
Patient Therapy Guide



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How to contact Medtronic

Contact us by phone

Our experienced Patient Services group is available to answer any questions or concerns you may have about your InterStim Therapy system.



To speak directly with a Patient Services representative call 1-800-510-6735. Our staff is available Monday through Friday from 8:00 AM to 5:00 PM (Central Time).

Contact us online

Medtronic is dedicated to providing you with the most up to date information available about your Medtronic InterStim Therapy system. Website information is available 24 hours a day at: www.interstim.com.

**To update or order a new registration
card contact:**

Medtronic Inc., Patient Services Department,
Mail Stop V25, 3850 Victoria Street North,
Shoreview, MN 55126-2978
(1-800-551-5544).

**Who should I contact if I have a
question or concern about my health
or InterStim Therapy settings?**

Always discuss any questions or concerns
you have about your health or InterStim
Therapy system settings with your doctor.
Your doctor is the appropriate person to
contact about your health or therapy
management. He or she has your medical
records and knows your medical history. As a
medical device manufacturer, Medtronic is not
able to comment on your medical condition.

How to contact Medtronic

Information about you and your InterStim Therapy system

Your personal information

Your doctor's name _____

Specialty _____

Phone _____

Your doctor's name _____

Specialty _____

Phone _____

Your nurse or clinician's name _____

Your medications _____

Information about you and your InterStim Therapy system

Emergency contact information

Name _____
Relationship _____
Phone _____

Name _____
Relationship _____
Phone _____

Your InterStim Therapy system information

Date of implant _____
Hospital where your neurostimulator was
implanted _____

Neurostimulator Model number _____
Serial # _____

Lead Model number _____
Serial # _____

Extension (if applicable)
Model number _____
Serial # _____

Information about you and your InterStim Therapy system

Patient Programmer

Model number _____

Serial # _____

Notes _____

Information about you and your InterSim Therapy system

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Glossary

The words that appear in **bold** in this *Patient Therapy Guide* are defined here for your convenience.

Amplitude – The strength or intensity of stimulation measured in volts.

Anus – The opening at the bottom of the rectum through which stool passes.

Bowel control – See fecal incontinence.

Bowel diary – A pocket-sized booklet used daily to record bowel symptoms.

Cardioverter Defibrillator – A small, implantable device which is used to treat heart beats that are too fast. Also referred to as an implantable cardioverter defibrillator or ICD.

Catheter – A small tube used to withdraw urine from the body.

Clinician – The term clinician is used in this guide to refer to a specialized medical professional such as a doctor, nurse,

Glossary

medical technician, specialist, or
Medtronic consultant.

Clinician programmer – The clinician programmer is a small hand-held electronic device used by a clinician, such as your doctor or nurse, to set up the operating features of an implanted neurostimulator. It is similar to the patient programmer.

Colon – The lower part of the large intestine, above the rectum.

Contraindication – Something that is absolutely not allowed, under any circumstances, because the risk outweighs any benefits.

Defecation – The evacuation of stool from the bowels, also known as a bowel movement.

Diathermy – A type of medical treatment that delivers energy to treat specific areas of the body. These treatments are typically used to relieve pain, stiffness, and muscle spasms, reduce joint contractures, reduce

Glossary

swelling and pain after surgery, and
promote wound healing.

Electromagnetic compatibility (EMC) – Fields of energy produced by certain types of equipment that use electricity and magnets may interfere with the normal operation of other electronic devices, such as an implanted neurostimulator. The energy fields created around electrical items can be strong or weak. The closer to the item you are, the stronger the energy field. Electromagnetic compatibility means that the electrical energy field generated by an electrical item is compatible with other electrically sensitive items such as an implanted heart device.

Electromagnetic interference (EMI) –

Everything that uses electricity produces a field of electromagnetic energy. This energy field surrounds the electrical item while it is connected to a source of electricity (even a battery source). The energy field is strongest near the item and weakens with distance from the item.

Glossary

Strong EMI often affects how electronic devices function.

Fecal incontinence – An accident or leaking involving stool (bowel control).

Hematoma – A localized swelling filled with blood resulting from a break in a blood vessel.

Incontinence (urinary) – Inability to control the flow of urine from the bladder.

Incontinence (fecal) – Inability to control the the escape of gas, stool, or liquid stool from the rectum.

InterStim Therapy system – A therapy in which an implanted stimulation system sends mild electrical pulses to the sacral nerve to help reduce bladder control or bowel control problems.

Lead – A small insulated wire which delivers electrical stimulation to a nerve or muscle.

Long-term lead – The type of implanted lead used for long-term InterStim Therapy.

Glossary

Magnetic Resonance Imaging (MRI) – A diagnostic method that produces computerized images of internal body tissues.

Neurostimulator – A small, implantable device that produces the mild electrical pulses for nerve stimulation.

Patient Programmer – A hand-held electronic device used by the patient to control amplitude and turn the neurostimulator on and off.

Rectum – The last 6 to 8 inches of the large intestine. The rectum stores solid waste until it leaves the body through the anus.

Retention (urinary) – Inability to empty the bladder. Patients suffering from this condition may be unable to start to void with no urine emptying from the bladder, or may start to void but be unable to completely empty the bladder.

Sacral nerves – Nerves located near the base of the spinal cord in the lower back. Sacral

nerves control the bladder, bowel, and pelvic organs.

Screener cable – The screener cable is used to connect the implanted lead to the external test stimulator during a test stimulation.

Seroma – A fluid-filled mass in a tissue or organ.

Stimulation – Electrical pulses generated by a neurostimulator.

Stool – Solid waste material eliminated from the body; also referred to as "feces."

Test stimulator – A battery-powered device, worn externally, that sends mild electrical pulses to the sacral nerve.

Ultrasound – High-frequency sound waves used to diagnose certain conditions.

Urge incontinence (urinary) – The involuntary loss of urine (incontinence) associated with a sudden, strong desire to void (urgency).

Glossary

Urgency-frequency (urinary) – An
uncontrollable urge to urinate that results
in frequent, small amounts of urine voided
as often as every 15 minutes.

Urinary – Relating to the system that makes
and releases urine.

Urinate – To release urine from the bladder.

Void – To release urine from the bladder.

Voiding diary – A pocket-sized booklet used
daily to record urinary symptoms.

Voiding dysfunction – Being unable to control
the frequency, timing, and amount of urine
voided when there is a need to go to the
bathroom.

Warning – An alert about possible injury or a
problem that may happen as you use or
misuse a device.

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How to use your *Patient Therapy* Guide



Your *Patient Therapy Guide* is designed to help you understand how the InterStim Therapy system works and to answer questions you may have about how the therapy may affect your day-to-day life.

InterStim Therapy can be prescribed to help the symptoms of urinary control or **bowel control** problems. The majority of the information is the same for both conditions, however where necessary the guide provides individual chapters to address each condition.

- Information specific to **urinary** control is found in Chapter 2.
- Information specific to bowel control is found in Chapter 3.

How the guide is organized

- Chapter 1, What is the InterStim Therapy system?
 - describes the **InterStim Therapy system** components and explains how the therapy works
- Chapter 2, How InterStim Therapy works to treat your urinary control symptoms
 - describes the body's **urinary** system
 - provides important guidelines for the test stimulation period
 - includes a sample **voiding diary**
- Chapter 3, How InterStim Therapy works to treat your bowel control symptoms
 - describes the body's bowel system
 - provides important guidelines for the test stimulation period
 - includes a sample of a **bowel diary**

- Chapter 4, Test stimulation for urinary control or bowel control
 - describes the InterStim Therapy test stimulation period
 - provides an overview of the procedure
 - answers commonly asked questions about the test stimulation period
- Chapter 5, Long-term InterStim Therapy
 - describes the implant procedure for the long-term **InterStim Therapy system**
- Chapter 6, Living with your InterStim Therapy system
 - provides important information about living with your implanted InterStim Therapy system, including any changes to daily activities
 - lists possible complications and precautions you should be aware of

- Appendix A, Electromagnetic interference (EMI)
 - describes the possible effects of **electromagnetic interference** on your implanted InterStim system
 - lists household and office appliances that do not cause electromagnetic interference problems
- Appendix B, Information for your doctors
 - provides a list of medical procedures that you can and cannot be exposed to when you have an implanted InterStim system
 - provides precautionary information intended for any **clinicians** who are providing medical or dental care for you
- Appendix C, Clinical trial results
 - provides results from clinical trials

Note: For information on how to use your InterStim Therapy **Patient Programmer**, read the manual provided with your patient programmer. If you have questions, contact your doctor.

Special notes

Some things to notice about your guide:

- Words that appear in **bold** lettering are defined in the Glossary found at the beginning of this guide.
- It is a very good idea to bring this guide along to all of your health care provider appointments and share this information with doctors, dentists, and other health care professionals who may not be familiar with the InterStim Therapy system.

Appendix B, Information for your doctors, on page 93, provides precautionary information for your doctors about medical procedures that may not be compatible with the InterStim Therapy system.

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How to use your Patient Therapy Guide

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1 What is the InterStim Therapy system?



InterStim Therapy is a treatment that may relieve **urinary control** or **bowel control** symptoms for some people for whom other treatments have not worked. The **InterStim Therapy system** has been implanted in over 50,000 patients worldwide.

The InterStim Therapy system uses mild electrical pulses to stimulate the sacral nerve located near the tailbone.

Stimulation will not cure your **urinary** control or bowel control problems. It may however reduce your symptoms to a tolerable level and allow you to resume many of your daily activities.

The InterStim Therapy system

The InterStim Therapy system includes three parts:

- a small **neurostimulator** device which generates mild electrical **stimulation**, similar to a pacemaker.
- a **lead** or insulated wire which is also implanted. One end of the lead is connected to the neurostimulator and the other end delivers mild electrical pulses to your sacral nerve area.
- a therapy control device, called a **Patient Programmer**. You can use this hand-held device to adjust the therapy or turn the therapy on or off. The programmer is used by holding it over the implanted neurostimulator.¹

What is the InterStim Therapy system? 1

Your **clinician** will also have a device to control the amount of therapy the **neurostimulator** provides.

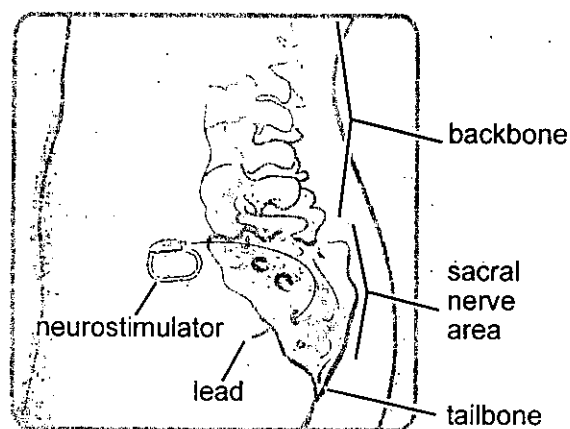


Figure 1.1 The implanted InterStim Therapy system.

¹ See the manual provided with your Patient Programmer for complete operating information.

What is the InterStim Therapy system? ¹

Your InterStim neurostimulator battery

Your InterStim **neurostimulator** is powered by a battery. The battery is sealed inside the neurostimulator and therefore cannot be replaced without replacing the entire neurostimulator.

As the battery strength depletes over time, eventually the battery will become too weak to power the neurostimulator. When this happens, you will need to have the neurostimulator surgically replaced.

How long the battery lasts depends on your **stimulation** settings and how often the neurostimulator is on. Like any battery-powered device, the more it is used and the higher the settings, the faster the battery power will be depleted.

The first time your neurostimulator is programmed, your doctor or nurse should be able to estimate how long your neurostimulator battery will last. This estimate is based on the initial programmed settings of

What is the InterStim Therapy system? 1

your neurostimulator. Any changes to your programmed settings will affect battery power over time.

The battery power of your neurostimulator will be checked at your follow-up appointments. An indicator will also appear on the screen of your **patient programmer** when the battery power is low. When the battery power is low, your doctor or nurse will talk to you about scheduling an appointment to replace the neurostimulator.

If you have any questions about how long your neurostimulator battery will last, talk to your doctor or nurse.

What is the InterStim Therapy system? 1

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What is the InterStim Therapy system? 1

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2 How InterStim Therapy works to treat your urinary control symptoms



Your doctor feels you might benefit from
Medtronic's InterStim Therapy.¹

In order to understand how the InterStim
Therapy system works for **urinary** control, it is

¹ Note: It is not known whether InterStim Therapy is safe
to use during pregnancy. For more information about
precautions related to the InterStim system, see
Chapter 6, Living with your InterStim Therapy system,
on page 71.

helpful to understand how the urinary system functions.

Your body's urinary system

Your body's urinary system includes the kidneys, ureters, bladder, and urethra.

The kidneys remove excess fluid and waste from the blood and continuously produce urine. The ureters carry urine from the kidneys to the bladder where urine is stored.

The urethra is the tube through which urine flows during urination.

As the bladder becomes full, a message is sent to the brain through the sacral nerve (located near the tailbone) that it is time to **urinate**. The brain then tells the bladder muscle, again through the sacral nerve, to contract and the pelvic muscles to relax. This allows the bladder to empty itself of urine.

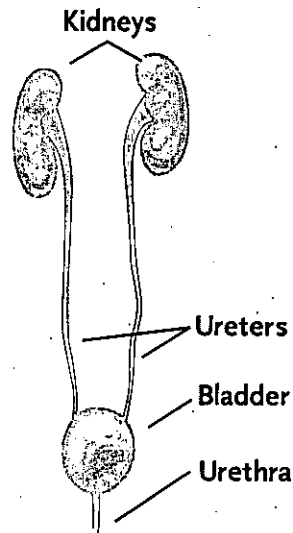


Figure 2.1
The Urinary System

It is believed that bladder control problems may be due to faulty communication between the brain and the bladder. Your body and brain communicate using your internal nervous system and if there is a problem with this

How InterStim Therapy works to treat your urinary control symptoms 2

communication, then you may have limited control over your bladder function.

Can the InterStim Therapy system help you?

This therapy has helped thousands of people with **urinary** control problems who did not respond to other treatments, such as a change in diet, medication, biofeedback, or catheterization.

Urinary urge incontinence – Involuntary loss of urine associated with a sudden, strong desire to **void**.

Urinary urgency-frequency – An uncontrollable urge to **urinate** that results in frequent, small amounts of urine voided as often as every 15 minutes.

Urinary retention – The inability to empty the bladder. If you have this condition, you may need to use a **catheter** to empty your bladder.

Sample voiding diary

You will receive a **voiding diary** from your doctor. A voiding diary is used to track your symptoms for a few days. This record of your symptoms will provide your doctor with valuable information.

You will be asked to:

- Before your test stimulation, record information, such as how often and how much you empty your bladder or experience symptoms.
- During your test stimulation, record how **stimulation** affects your symptoms.
- After your test stimulation, monitor any return of symptoms.

You may need to complete several diaries before, during, and after your test stimulation. It is important to complete the diary accurately in order to give your doctor a detailed picture of how the InterStim Therapy works for you. A complete record may also be important for your insurance company.

How InterStim Therapy works to treat your urinary control symptoms 2

The diary is small enough to tuck into a purse or pocket so that you can carry it with you. Each time you experience symptoms, jot down or circle the correct information. It takes just a moment to do this, but the information is very important. It will help you and your doctor determine whether an InterStim Therapy system can help you.

How to use your voiding diary

The diary provides an area inside the front cover for you and your doctor to indicate which stage of the treatment is being recorded. The summary page inside the back cover, has an area where you give a short description of your symptoms over the previous days. You have space to record symptoms for several days. Your doctor will give you additional diaries if you need them.

Your doctor or nurse will show you how to complete the **voiding diary**. If you have questions later, contact your doctor or nurse. Be sure to bring the diary with you when you visit the doctor's office again.

Diary for urinary control symptoms

Each time you **urinate** or experience symptoms, complete one column in the chart. Begin with the date and time, and work down the column, following steps 1-6 as instructed by your doctor.

1. Volume voided into measuring cup. You will be given a cup marked in milliliters. Urinate into the cup and write down the number of milliliters you have urinated.
2. Volume measured by **catheter**. Record this information only if you use a catheter.
3. Leaking episode. If you leak urine, you need to estimate the amount of the leak. Choose from None to Heavy and circle the appropriate term.
4. Change of pad or diaper. Circle yes or no to indicate whether you had to change a pad or diaper because of leaking.

How InterStim Therapy works to treat your urinary control symptoms 2

How InterStim Therapy works to treat your urinary control symptoms 2

5. Did you feel empty after voiding? Circle yes or no to indicate whether your bladder felt empty after you urinated or leaked.
6. Degree of urgency prior to voiding. Indicate the strength of the urge you felt before you urinated compared to other times you've voided. Circle the appropriate term.

See Figure 2.2 for an example of a urinary control voiding diary.

Please record date and time and answer every question
each time you go to the toilet and/or have a leaking episode.

Date:	5/6/08	5/6/08	5/6/08	5/6/08	5/6/08
Time:	7 a.m.	10 a.m.	2 p.m.	4 p.m.	7 p.m.
1. Volume voided into measuring cup.	300 ml	250 ml	300 ml	300 ml	250 ml
2. Volume measured by catheter.	ml	ml	ml	ml	ml
3. Please rate any leaking episode you experienced. Slight = a few drops Moderate = 1-2 tablespoons (15-30 ml) Heavy = soaks pad/diaper or outer clothing	None	Slight	Slight	Slight	Slight
4. Did leaking cause you to replace your pants?	No	Yes	No	No	No
5. Did you feel empty after voiding?	No	Yes	No	No	No
6. Degree of urgency prior to voiding?	Mild	Mild	Mild	Mild	Mild

Figure 2.2 Example of urinary control voiding diary.

How InterStim Therapy works to treat your urinary control symptoms 2

Steps for a successful test stimulation period

You can help make the test stimulation a success by doing the following:

- Do not drink more or less than usual.

For the test to be successful, you want to test how your body, with the help of the **stimulation**, handles a typical intake of liquids.

- Don't try to hold your urine.

You may find that you can go longer without voiding or leaking and may want to test your body's new ability to hold urine. Don't do this. Allow your bladder to determine when it needs to be emptied. Holding urine will interfere with measuring the effect of the therapy.

- **Void** only when you feel the urge to go.

You've probably learned ways to manage your symptoms and avoid embarrassing episodes. Perhaps you visit the rest room as soon as you enter a restaurant or

shopping center. Perhaps you go every half hour; whether or not you feel the urge. During the test stimulation period, void only when you feel the urge to urinate or when you sense that your bladder is full. This practice will help you get into a more regular voiding schedule.

- Record each urination or leaking episode in your diary.

You and your doctor will need complete, accurate information in order to determine if an InterStim Therapy system is right for you.

How InterStim Therapy works to treat your urinary control symptoms 2

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How InterStim Therapy works to treat your urinary control symptoms 2

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3 How InterStim Therapy works to treat your bowel control symptoms



Bowel control problems, can be uncomfortable, embarrassing, and frustrating.

You and your doctor may have tried several therapies that have not been successful in treating your bowel control problem. You may have changed your diet, used medications, increased your exercise, undergone biofeedback, or had surgery for your bowel control problem.

Your doctor believes that you might benefit from InterStim Therapy, which may provide relief from your symptoms and allow you to return to a more desired lifestyle.

This therapy has helped thousands of people with bowel control problems who did not respond to other treatments, such as a change in diet, medication, or biofeedback.

Your body's bowel system

In order to understand how the **InterStim Therapy system** works for bowel control it is helpful to understand how the bowel system functions. Bowel control depends on the coordinated effort of many different muscles and nerves. Any problem with the function of one or more of these muscles or nerves can lead to bowel control problems.

Depending on the cause and the severity of the problem, treatments such as changes in diet and exercise, medications, or surgery may be used.

Continence, the ability to hold **stool** until an appropriate time, depends on the consistency of the stool and the following:

- ability of the **rectum** to hold stool
- ability of the nerves to send signals when the rectum is full
- ability of the anal sphincter muscles to hold the **anus** closed

You can experience **incontinence** if any of these areas do not function properly.

Bowel control symptom descriptions

The following symptom definitions will help you describe your **bowel control** problems when filling out the **bowel diary**.

Staining – Accident caused stain on buttocks, pad, diaper or clothing.

Minor soiling – Accident was small enough that an immediate change of pad, diaper, or clothing was not necessary.

How InterStim Therapy works to treat your bowel control symptoms 3

Major soiling – Accident requires immediate change of pad, diaper, or clothing.

Sample bowel diary

A **bowel diary** is used to track your symptoms for a few days. It will provide your doctor with valuable information.

You will be asked to:

- Before your test stimulation, record information, such as how often and how much you empty your bowels or experience symptoms.
- During your test stimulation, record how **stimulation** affects your symptoms.
- After your test stimulation, monitor any return of symptoms.

You may need to complete several diaries before, during, and after your test stimulation. It is important to complete the diary accurately in order to give your doctor a detailed picture of how the InterStim Therapy works for you. A complete record may also be important for your insurance company.

The diary is small enough to tuck into a purse or pocket so that you can carry it with you. Each time you experience symptoms, jot down or circle the correct information. It takes just a moment to do this, but the information is very important. It will help you and your doctor determine whether an InterStim Therapy system can help you.

How to use your bowel diary

The diary provides an area inside the front cover for you and your doctor to indicate which stage of the treatment is being recorded. The summary page inside the back cover has an area where you give a short description of your symptoms over the previous several days. You have space to record symptoms for several days. Your doctor will give you additional diaries if you need them.

Your doctor or nurse will show you how to complete the **bowel control** diary. If you have questions later, contact your doctor or nurse.

How InterStim Therapy works to treat your bowel control symptoms 3

Be sure to bring the diary with you when you visit the doctor's office again.

Diary for bowel control symptoms

1. Begin this diary when instructed by your clinician.
2. Record all bowel episodes occurring during the period as directed by your clinician.
3. Record only one bowel episode per column.

A bowel episode is considered any the following:

- **Defecation:** bowel movement in the toilet (continent event).
 - **Fecal incontinence:** accident or leaking involving **stool**.
4. Answer all the questions.
 5. Choose only one answer per question.

6. If you complete the diary, continue recording bowel episodes with another diary.
7. If you have a day without any accidents or bowel episodes, fill-in the date and check the "No Episodes" box.
8. If you have any questions concerning this diary, please call your physician.

See Figure 3.1 for an example of a bowel control diary.

How InterSlim Therapy works to treat your bowel control symptoms 3

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Figure 3.1 Example bowel control diary.

<p>Date: <u>Sept 3, 2008</u></p> <p><input checked="" type="checkbox"/> No Bowl Episodes Today</p> <p>Time of Episode: <u>4:15</u> AM PM</p> <p>1. Amount of Incontinence (see definitions on pg. 3)</p> <p><input type="checkbox"/> None <input type="checkbox"/> Minor soiling <input checked="" type="checkbox"/> Major soiling</p> <p>2. Did you have to hurry or rush to the toilet urgently for this episode? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>3. Brief description (circle one number below, using the pictures below)</p> <p>1 2 3 4 5 6 7</p> <p>4. Did the episode occur during your nighttime sleep or wake you from nighttime sleep? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes</p>	<p>1 Pelvis</p> <p>2 Formed & hard</p> <p>3 Formed & soft</p> <p>4 Semi-formed</p>
<p>Date: <u>Sept 4, 2008</u></p> <p><input checked="" type="checkbox"/> No Bowl Episodes Today</p> <p>Time of Episode: <u>5:10</u> AM PM</p> <p>1. Amount of Incontinence (see definitions on pg. 3)</p> <p><input type="checkbox"/> None <input type="checkbox"/> Minor soiling <input checked="" type="checkbox"/> Major soiling</p> <p>2. Did you have to hurry or rush to the toilet urgently for this episode? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>3. Brief description (circle one number below, using the pictures below)</p> <p>1 2 3 4 5 6 7</p> <p>4. Did the episode occur during your nighttime sleep or wake you from nighttime sleep? <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes</p>	<p>5 Intestine</p> <p>6 Loose</p> <p>7 Watery</p>
<p>Date: <u>Sept 5, 2008</u></p> <p><input type="checkbox"/> No Bowl Episodes Today</p> <p>Time of Episode: <u>5:10</u> AM PM</p> <p>1. Amount of Incontinence (see definitions on pg. 3)</p> <p><input type="checkbox"/> None <input type="checkbox"/> Minor soiling <input checked="" type="checkbox"/> Major soiling</p> <p>2. Did you have to hurry or rush to the toilet urgently for this episode? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>3. Brief description (circle one number below, using the pictures below)</p> <p>1 2 3 4 5 6 7</p> <p>4. Did the episode occur during your nighttime sleep or wake you from nighttime sleep? <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes</p>	<p>8 Watery</p>
<p>Date: <u>Sept 6, 2008</u></p> <p><input type="checkbox"/> No Bowl Episodes Today</p> <p>Time of Episode: <u>5:10</u> AM PM</p> <p>1. Amount of Incontinence (see definitions on pg. 3)</p> <p><input type="checkbox"/> None <input type="checkbox"/> Minor soiling <input checked="" type="checkbox"/> Major soiling</p> <p>2. Did you have to hurry or rush to the toilet urgently for this episode? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>3. Brief description (circle one number below, using the pictures below)</p> <p>1 2 3 4 5 6 7</p> <p>4. Did the episode occur during your nighttime sleep or wake you from nighttime sleep? <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes</p>	<p>9 Watery</p>

Figure 3.1 Example bowel control diary.

4 Test stimulation for urinary control or bowel control



If your doctor feels you are a candidate for the InterStim Therapy system, you will be scheduled for a test stimulation.

The test stimulation allows you to experience the effects of InterStim Therapy at home for a short period of time. Based on the results of the test stimulation, your doctor can determine if the InterStim Therapy system may be beneficial for you.

Before deciding to try an InterStim test stimulation, your doctor or nurse will review your medical history with you and will ask you to write down your urinary or bowel habits in a diary.

This information will be used to decide if an InterStim Therapy system would be helpful.

What is test stimulation?

Your doctor will discuss the test stimulation procedure with you and the options for using either a temporary **lead** or **long-term lead** for the test.¹ One end of the lead is implanted near your **sacral nerves** and the other end is connected to a small external **test stimulator** that can be worn on a belt. The stimulator generates mild electrical pulses that are carried to the sacral nerve by the lead.

While you wear the test stimulation system you will need to complete a diary to record how the **stimulation** affects your symptoms.

¹ The option to use two temporary test leads is also possible. Only one lead will be actively stimulating at a time.

At the end of the test stimulation period, you and your doctor will decide if an InterStim Therapy system is the right choice for you.

The test stimulation procedure

You may want to bring a spouse, relative, or friend to provide support during the procedure.

The surgery may be done in an operating room while you are under general anesthesia or your doctor may give you a mild anesthetic along with local sedation so that you can provide feedback during the procedure.

During your procedure, your doctor will insert a needle just above your tailbone to locate the appropriate sacral nerve. When the needle is in place, the test stimulation system will be turned on and your doctor will ask you to describe what you feel.

Some people feel a "pulling" or "tingling" sensation in their pelvic muscles or big toe. Women may feel a sensation in the vaginal area, men in the scrotum.

Test stimulation for urinary control or bowel control 4

If you do not feel the sensation, your doctor will slowly increase the **stimulation** until you do. The sensation should not be painful.

Some people have trouble feeling the stimulation or feel no stimulation at all. However, regardless of whether you feel the stimulation or not, your doctor will verify that the test stimulation **lead** is in the correct position by looking for a muscle response in your buttocks and big toe (the same nerve causes a muscle response in both places).

Once the correct sacral nerve and responses have been confirmed, the lead is placed at that site. If the **long-term lead** is used, it is fully implanted under the skin. If the temporary lead is used, just one end of the temporary lead is implanted under the skin.

The long term lead or the temporary lead is connected to the **test stimulator**. When the system is in place, an x-ray may be taken to confirm the position of the lead.

The nursing staff will work with you to find the most comfortable way to wear the **test stimulator**.

Operating the test stimulator

After confirming that the test stimulation lead is in the correct position, your doctor or nurse will show you how to operate the test stimulator and also inform you of precautions related to the test stimulation system and of activity restrictions.

The sensation of **stimulation** should not be painful. Most people describe it as a slight pulling or tingling in the pelvic area. If you experience any pain, turn the test stimulator down or off and notify your doctor or nurse.

During the test stimulation period

Keeping a diary

During the test stimulation period, you will be asked to complete a diary. You will use it to track your bladder control symptoms or bowel

Test stimulation for urinary control or bowel control 4

control symptoms. This history will help your doctor evaluate whether an InterStim Therapy system is right for you.

Your doctor may provide you with a diary. You may also want to create your own diary in a simple notebook. For an example page of a diary:

- For a urinary control diary, see "Sample voiding diary" on page 37.
- For a bowel control diary, see "Sample bowel diary" on page 48.

Test stimulation for urinary control or bowel control 4

Important safety information about test stimulation

Due to the temporary nature of the test stimulation, you need to be aware of certain **warnings** and precautions that apply to you during the test stimulation period.

WARNINGS:

Note: Only a few of these warnings and precautions also apply to the long-term implanted system.

- DO NOT have **diathermy**. Refer to "Diathermy" on page 94 for more information.
- Turn the **test stimulator** off when you drive a car or use power tools. Brief increases in **stimulation** due to lead movement could startle you and cause you to lose control of these devices and hurt yourself or others.
- (**Urinary** control therapy only) This therapy is not intended for you if you have a mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

PRECAUTIONS:

The following precautions should be observed during the test stimulation period.

Test stimulation for urinary control or bowel control 4

Test stimulation for urinary control or bowel control 4

- Call your doctor if you see any redness or swelling at the **lead** site. This could be a sign of infection.
- During the test stimulation period, avoid sexual activity to ensure the test stimulation lead stays in place.
- Limit your physical activity to low or moderate levels.
- Take it easy during the test stimulation period. Avoid bending, stretching, or lifting heavy objects. Be aware that the test stimulation lead can move, which may cause the **stimulation** to increase or decrease suddenly. Quick movements or straining could increase the stimulation level you feel and cause temporary minor discomfort.
- Avoid baths and showers. Take sponge baths, but be careful to keep the area around the lead dry and undisturbed.

- If you see any of your health care providers during the test stimulation period, inform them that you have a test stimulation lead.
- Ask your doctor what to do if you feel a change in **stimulation** when you stand up, walk, or change positions. You may need to adjust the **test stimulator**. Remember, the goal is to feel moderate stimulation.
- Adjust the test stimulator if the stimulation becomes uncomfortable. Turn the "A" dial to OFF and then slowly turn it up again until you feel moderate stimulation.
- Call your doctor or nurse if you feel any sensation near the ground pad. It may need to be checked to see whether it has moved.

Test stimulation results

Generally, if your symptoms improved and you didn't experience any problems during the test stimulation period, then you and your doctor will discuss whether to proceed with a long-term InterStim Therapy system.

Test stimulation for urinary control or bowel control 4

If your test stimulation results using the temporary test stimulation lead are inconclusive, your doctor may recommend a second test stimulation using a long-term lead or recommend a different treatment option.

Common questions

I'm not sure if the stimulation is working. What should I do?

Check the battery and the ON light to be sure the **test stimulator** is working. If it is, turn the **amplitude** dial to OFF and gradually turn up the **stimulation** to a comfortable setting. Call your doctor if you have any questions or are still unsure that the test stimulator is working.

What does the stimulation feel like?

Stimulation varies from person to person, but most people describe it as a slight "pulling" or a "tingling" sensation in the pelvic area. It should not be painful. If you feel any pain, turn off the test stimulator, and call your doctor.

Will the test stimulation cure my condition?

No. The test stimulation is temporary. It is a tool that helps determine whether an InterStim Therapy system is appropriate for you. Once the lead is removed, your original symptoms will return.

If you have had positive results with the test stimulation, then you and your doctor may decide to use a long-term InterStim Therapy system to treat your symptoms.

Will the stimulation change at all?

You may feel slight **stimulation** changes when you move from a sitting to a standing position or from a standing to a walking position. Check with your doctor; you may need to adjust the stimulation when that happens.

Will stimulation hurt my nerves?

No. Research has shown that the nerves are not harmed by the stimulation when used properly.

Test stimulation for urinary control or bowel control 4

How long will the battery last?

Your **test stimulator** will have a new 9-volt battery when you go home. It should last for the entire test stimulation period. However, you can change the battery, if necessary, by opening the battery door on the back of the device.

Turn off the test stimulator before removing the batteries (and do not leave the battery compartment of the test stimulator empty for any long periods of time). When the new battery is in place, close the battery door and slowly turn up the **stimulation** setting to a comfortable level.

Can I have sex during the test stimulation period?

No, you should avoid sexual activity during the test stimulation period because it could cause the **lead** to move. This restriction only applies to the test stimulation period, there are no restrictions on sexual activity during long-term InterStim Therapy.

5 Long-term InterStim Therapy



If you had good results during the test stimulation period, you and your doctor may choose to use the InterStim Therapy system for long-term treatment of your symptoms.¹

¹ If for any reason you or your doctor decides to discontinue this therapy, the InterStim Therapy system can be turned off or removed. Your doctor may choose not to remove the implanted lead based on the condition of the lead and your individual case.

The implant procedure

Your doctor performs the implant procedure for the long-term InterStim Therapy in an operating room.

The **neurostimulator** is usually implanted in the upper buttock, but it may be implanted in the abdominal area depending on your type of neurostimulator system. Please discuss any concerns you have about implant location with your doctor.

The neurostimulator is connected to the **long-term lead** and tested to make sure the **stimulation** is effective.

Risks of surgery

Please discuss any concerns you have about surgery with your doctor. Implanting an InterStim Therapy system has risks similar to any surgical procedure, including swelling, bruising, bleeding, and infection.

Before surgery, be sure to tell your doctor about any medications that you are currently taking. Depending on the medication, you

Long-term InterStim Therapy 5

might be at greater risk for postoperative complications.

When your InterStim Therapy stimulation is turned on

Your doctor or nurse may turn on the InterStim Therapy stimulation before you leave the hospital, or you may be instructed to wait until you get home to turn it on.

The sensation that you experience will be similar to what you felt during test stimulation. It should not be painful. If you do experience pain, use your **patient programmer** to turn the neurostimulator stimulation down or completely off, and contact your doctor.

You and your doctor may adjust the level of **stimulation** as necessary to achieve the best symptom control. Your doctor or nurse can show you how to adjust the stimulation level of the neurostimulator. You can also refer to the manual provided with your patient programmer for complete instructions.

Caring for yourself after surgery

You should be able to go home the same day that you have surgery. Your incisions may feel sore and painful, especially during the first two weeks. Your doctor may prescribe medication to control your discomfort. Avoid activities that may cause the implanted **lead** to move or that may damage the neurostimulator.

Gradually increase your activity level as your incisions heal. On your doctor's advice and as you feel better, you should be able to resume an active lifestyle. You should be able to shower or bathe as before and enjoy normal activities (such as travel, have sex, go to work, walk, hike, work in the garden, and so on).

You will have to make some adjustments in your activities, such as turning off the **neurostimulator** when you operate a vehicle, or being more aware of theft-prevention devices in stores. See "Daily activities" on page 73.

Once normal activity is resumed, some patients find that the lead or neurostimulator is

not placed in the most comfortable position. In some cases, patients may need surgery to reposition or replace the **lead** or **neurostimulator**. This surgery does not require an overnight hospital stay.

Follow-up appointments

Your doctor or nurse will schedule follow-up appointments to review your progress. In the beginning, you may need to go in more often to adjust **stimulation** settings. Always bring your patient programmer with you to your follow-up appointments.

Your patient identification card

Before you leave the hospital, you should receive a temporary patient identification card. After your implant registration card is received from the hospital, Medtronic will send you a permanent patient identification card.

Your patient identification card provides information about you, your implanted device, and your doctor. Carry this card with you at all times. Your patient identification card will

Long-term InterStim Therapy 5

identify that you have an implanted device in the case of any emergency, and it may also allow you to bypass security devices at airports.

If you move, change doctors, or lose your card, contact Medtronic for a replacement card. See "How to contact Medtronic" on page 3 at the beginning of your *Patient Therapy Guide*.

6 Living with your InterStim Therapy system



The InterStim Therapy system is intended to treat urinary control symptoms and/or bowel control symptoms so you can regain control of your life.

To help make living with your InterStim Therapy system a positive experience, please review this chapter for important information about your InterStim Therapy system.

The following are important areas of your life that may be affected by the InterStim Therapy system:

- **Daily and recreational activities:**

There are some activities that may dislodge, move, or damage parts of your InterStim Therapy system.

- **Medical procedures:**

Certain medical procedures should either not be performed on anyone with an implanted device, or should be performed only under specific guidelines.

Please review the information found in this chapter and in Appendix B, Information for your doctors, on page 93.

- **Possible effects of some electrical items:**

Some electrical items can cause interference with the normal operation of the InterStim Therapy system. For complete information, see Appendix A, Electromagnetic interference (EMI), on page 83.

Daily activities

Avoid activities that put undue stress on the implanted components of your **InterStim Therapy system**

- Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause parts of your implanted system to fracture or move out of place.

This can result in a loss of **stimulation**, intermittent stimulation, stimulation at the fracture site, and additional surgery. For details, see "Recreational activities" on page 75.

- Do not rub or handle your **neurostimulator** at the implant site

This could damage your system, cause the skin to thin or tear over the neurostimulator, or cause stimulation at the implant site.

How you move your body may affect how the stimulation feels. Quick movements or a

change in posture may move the implanted **lead** closer to your sacral nerve. This can feel like an unexpected increase in **stimulation**, even though the stimulation level has not changed.

Although the majority of patients do not experience this perceived "overstimulation" as bothersome, some have reported it as startling and unpleasant at times, causing them to lose control of equipment they were operating.

Note: Always carry your **patient programmer** with you so that you can adjust the stimulation level if needed.

If at any time you find stimulation bothersome use your patient programmer to turn the neurostimulator down or off. Tell your doctor if you experience any significant or recurring problems.

Living with your InterSlim Therapy system 6

Recreational activities

Although you should be able to do most activities you did before surgery, there are some activities which may cause discomfort or affect your implanted neurostimulator. Review the following information, and if you have any concerns or questions about these or other activities, contact your doctor.

Activities you should avoid

You should avoid activities that involve sudden, excessive, or repetitive bending, twisting, bouncing, or stretching. These movements could damage or move your implanted lead or affect the implanted neurostimulator. Examples of such activities include: gymnastics, mountain biking, and any other sport or activity that involves the movements described above.

Activities you can continue

Activities that should not affect your implanted InterStim Therapy system include running, jogging, walking, road biking, swimming, sexual activity, etc.

Living with your InterStim Therapy system 6

Precautions

- **Scuba diving or hyperbaric chambers** – Do not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters (33 feet) of water or above 2.0 ATA can damage your implanted InterStim Therapy system. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with your doctor.
- **Skydiving, skiing, or high-altitude activities** – High altitudes should not affect the InterStim Therapy system; however, you should consider the movements involved in any planned activity and take care to not put undue stress on your implanted InterStim Therapy system. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the lead, requiring additional surgery to repair or replace the lead.

Medical Procedures

Precautions

It is possible that there may be complications with your implanted InterStim Therapy system. These complications are unlikely, but you should be aware that they may happen. There are also known affects of some medical procedures, which could affect or damage your InterStim Therapy system.

For details, refer to the information starting on page 77 regarding:

- Possible complications
- Effects on other implanted devices
- Prohibited medical procedures
- Precautionary medical procedures

Possible complications

Possible complications for an implanted InterStim Therapy system will vary from person to person. Some of these possible complications may require surgical intervention.

Living with your InterStim Therapy system 6

- There could be undesirable changes in **stimulation**, possibly related to how the tissue may change around the tip of the **lead** where the mild electrical pulse is delivered.
- The position of the lead could change or the lead itself could fracture. Lead connections could also become loose.
- The lead or **neurostimulator** could shift from the original implant site or wear through the skin.
- The implanted materials could cause an allergic or immune system response.
- Your InterStim Therapy system might unexpectedly cease to function due to battery depletion or other causes.

If you are concerned or feel that you might be experiencing any of these conditions, contact your doctor.

Effects on other implanted devices

If you have or in the future require any other implantable medical device (such as a pacemaker, defibrillator, or drug pump), be sure to let your attending doctor know. Consult your InterStim Therapy doctor for appropriate precautions.

Prohibited medical procedures

The following medical therapy cannot be performed on anyone with an implanted InterStim Therapy system.

Diathermy

Inform anyone treating you that you **CANNOT** have any **diathermy** anywhere on your body because you have an implanted InterStim Therapy system. For additional information, see "Diathermy" on page 94.

Precautionary medical procedures

Before you undergo tests or treatments, always tell your medical and dental professional that you have an implanted InterStim Therapy system.

It is also a very good idea to bring this manual to all of your health care provider appointments and to share this information with your health care professionals who may not be familiar with the InterStim Therapy system.

Most routine diagnostic tests such as fluoroscopy or x-ray should not affect the InterStim Therapy system. However, the following medical equipment and treatments may adversely affect you and your InterStim Therapy system:

- Heart defibrillators
- Lithotripsy and electrocautery
- **Magnetic resonance imaging (MRI)**
- Radiation therapy over the neurostimulator
- Radio-frequency (RF)/microwave ablation
- **Ultrasound** or scanning equipment

- Other: bone growth stimulators, dental drills, electrolysis, laser procedures, psychotherapeutic procedures, transcutaneous electrical nerve stimulation (TENS), and therapeutic magnets

Refer your health care providers to Appendix B, Information for your doctors, on page 93.

Exposure to electromagnetic interference (EMI)

For important information about how EMI may affect your implanted system, see Appendix A, Electromagnetic interference (EMI), on page 83.

Living with your InterStim Therapy system 6

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Living with your InterStim Therapy system 6

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Appendix A Electromagnetic interference (EMI)



Everything that uses electricity produces a field of electromagnetic energy. This energy field surrounds the electrical item while it is connected to a source of electricity (even a battery source).

The energy field is strongest near the item and weakens with distance from the item. This electromagnetic field can sometimes interfere with other electronic devices.

This interference is referred to as **Electromagnetic Interference or EMI**.

If the energy fields affect your implanted device, this is referred to as electromagnetic interference or EMI. Most electromagnetic energy fields are small and weak and do not affect your neurostimulator.

Several safeguards are built into your neurostimulator to shield it from strong electromagnetic fields. For example, the metal case of your neurostimulator acts as a shield against electromagnetic fields.

Because the electromagnetic fields surrounding an electrical item get weaker the farther you are from the item, you can avoid potential EMI problems by keeping your neurostimulator a minimum distance away from the electrical item; the minimum distance for most items is 4 inches (10 cm).

Electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a neurostimulator. However, strong sources of EMI can result in the following:

- Serious patient injury or death, resulting from heating of the implanted components of the InterStim Therapy system and damage to surrounding tissue, for more information, see "Diathermy" on page 94.
- System damage, resulting in a loss of or change in symptom control and requiring additional surgery.
- Operational changes to the neurostimulator that can cause it to turn on or off (particularly in a neurostimulator enabled for magnet use¹) or to reset to the power-on-reset (POR) values, resulting in loss of **stimulation**, return of underlying symptoms, and in the case of POR, requiring your health care provider to reprogram your neurostimulator.

¹ Only applies to Model 3023 InterStim neurostimulator.

- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation.

Although the unexpected change in stimulation could feel uncomfortable, it does not damage the InterStim Therapy system or injure a patient directly. In rare cases, as a result of the unexpected changes in stimulation, patients have fallen down and been injured.

Even when the therapy is turned off, interference can affect the **lead(s)**. If you suspect EMI, move away from the source of the EMI. If possible, turn off the suspected source of EMI. Then use your **patient programmer** to turn your therapy on or off.

Safe from interference

Most household appliances and equipment that work properly and are properly grounded will not interfere with the **InterStim Therapy system**. The minimum safe distance for most

items is 4 inches (10 cm) from your **InterStim Therapy System**.

The following equipment is safe if you follow these guidelines:

- **Computer disk drives:** Keep the neurostimulator away from disk drives.
- **Induction range:** Keep the neurostimulator away from the burners while the burners are turned on.
- **Freezer, refrigerator, or storm doors:** Do not lean against the magnetic strip that holds the door closed.
- **Power tools:** Keep the motor away from the neurostimulator, lead, and extension.
- **Radio-frequency sources:** Keep AM/FM radios, and cellular, cordless, and conventional telephones at least 10 cm (4 in) away from the implanted neurostimulator.
- **Sewing machine or salon hair dryers:** Keep the neurostimulator away from the motors.

Appendix A
Electromagnetic interference (EMI)

- **Stereo speakers and radios for the home or car:** These items contain magnets. Do not lift or carry them close to or touching the part of your body where the neurostimulator is located.
- **Therapeutic magnets (eg, magnetic mattresses, blankets, wrist wraps, elbow wraps):** Keep the magnet at least 10 inches (25 cm) away from your neurostimulator. Magnetic fields of 10 gauss or less will generally not affect the neurostimulator.

Theft detectors and security gates

Walking through some theft detectors or security gates can cause an increase in **stimulation** or additional stimulation. It could also turn on or turn off your **neurostimulator**.

Use care when approaching theft detector or security arches or gates (such as those found in airports, libraries, and some department stores). If an airport security wand is used, ask

the security personnel to avoid placing the wand over your neurostimulator.

When approaching these devices, do the following:

1. If security personnel are present, show the security personnel your patient identification card for the neurostimulator and request a manual search.
2. If you must pass through the theft detector or security gate, turn your neurostimulator off, approach the center of the device and walk through normally.
 - If two security gates are present, walk through the middle, keeping as far away as possible from each gate.
 - If one gate is present, walk as far away as possible from it.

Note: Some types of security gates or theft detectors may not be visible.

3. Proceed through the security gate. Do not touch, lean on, or linger near the security gate device.

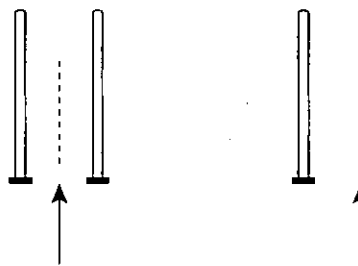


Figure A.1 Walking through security gates.

4. After you pass through the security gate, turn your neurostimulator on again.

Other possible sources of EMI

The following equipment or environments should be avoided because EMI is likely:

Antennas of citizen band (CB) or ham radios, electric arc welding equipment, electric induction heaters, electric steel furnaces, high-power amateur transmitters, high-voltage areas (generally safe if outside the fenced

area), linear power amplifiers, magnetic degaussing equipment, magnets and other equipment that generate strong magnetic fields, microwave communication transmitters (generally safe if outside the fenced area), perfusion systems, resistance welders, television and radio transmitting towers (generally safe if outside the fenced area).

What to do if you suspect EMI is affecting your device

If you suspect that some type of electrical equipment is interfering with the InterStim Therapy system, do the following:

1. Move away from the equipment or object.
2. If possible, turn off the equipment or object.
3. If necessary, use the **patient programmer** (or control magnet) to return the neurostimulator to the desired on or off state.
4. Inform the equipment owner or operator about the interference.

If the above actions do not resolve the effects of the interference, or you suspect that your therapy is not the same after exposure to **EMI**, contact your doctor.

Electromagnetic interference (EMI) Appendix A

Appendix B Information for your doctors



Bring your *Patient Therapy Guide* to all your medical and dental appointments, especially to appointments with those medical professionals who may not be aware of your implanted InterStim Therapy system.

This section of your guide provides important information to your doctors about medical procedures that are not compatible with your InterStim Therapy system or procedures that require special instructions.

Contraindications

Diathermy

Anyone who has an implanted InterStim Therapy system¹ CANNOT have any shortwave **diathermy**, microwave diathermy, or therapeutic **ultrasound** diathermy (all now referred to as diathermy) anywhere on their body. The energy generated by the diathermy process can be transferred through the implanted system and can cause tissue damage which could result in severe injury or death.

Diathermy can also damage parts of the InterStim Therapy system. This can result in loss of therapy from the neurostimulator, and can require additional surgery to remove or replace parts of the InterStim Therapy system.

¹ The InterStim Therapy system may consist of either an implanted lead only or implanted lead and neurostimulator. Depending on the neurostimulator model you have, your InterStim Therapy system may also have a lead extension.

Personal injury or device damage can occur during diathermy treatment when:

- the InterStim Therapy system is turned on or off.
- diathermy is used anywhere on the body (not just where the InterStim Therapy system is located).
- diathermy is used to deliver heat or no heat.
- any component of the InterStim Therapy system remains in the body, including **lead**, extension, or neurostimulator.

Medical procedures

Before you have any medical procedure, always inform all health care personnel that you have an implanted InterStim Therapy system. It is possible that you may suffer harm if the procedures are not compatible with your implanted system.

Information for your doctors Appendix B

WARNINGS about medical procedures

The following medical procedures can damage the neurostimulator, interfere with neurostimulator operation, or cause the patient harm. If these procedures are required, health care professionals should follow these guidelines. Also see Table B.1, "Medical procedures: EMI-related warnings and effects," on page 102.

Diathermy

See "Contraindications" on page 94.

Defibrillation and cardioversion

When the patient is in ventricular or atrial fibrillation, the first consideration is the patient's survival. External defibrillation or cardioversion can damage an InterStim Therapy system and cause induced electrical currents through the **lead** and extension. These induced electrical currents could injure the patient. The current flowing through the InterStim Therapy system should be minimized as follows:

- Paddles should be positioned as far from the neurostimulator as possible.
- Paddles should be positioned perpendicular to the neurostimulator.
- The lowest clinically appropriate energy output (watt/seconds) should be used for the defibrillation. After external defibrillation, a trained InterStim Therapy **clinician** should confirm that the InterStim Therapy system is working as intended.

Electrocautery

If electrocautery tools are used near an implanted neurostimulator or make contact with a neurostimulator, the following effects can occur:

- The insulation on the **lead** or extension can be damaged, which can cause the lead or extension to fail or to induce currents that damage tissue or stimulate or shock the patient.
- The neurostimulator can be damaged causing **stimulation** to temporarily decrease or increase.

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- The neurostimulator can be turned off by resetting the device to power-on-reset values (requiring the neurostimulator to be reprogrammed).

If electrocautery is necessary, these precautions must be followed:

- Turn off the neurostimulator before using electrocautery.
- Use bipolar cautery.
- Use only low-voltage modes if unipolar cautery is necessary.
- Use the lowest possible power setting.
- Place the current path (ground plate) as far away as possible from the neurostimulator, extension (if applicable), and **lead**.
- Do not use full-length operating-room-table grounding pads.

After electrocautery, a trained InterStim Therapy **clinician** should confirm that the neurostimulator is working as intended.

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High-output ultrasonics/lithotripsy

Use of high-output ultrasonics or lithotripsy is not recommended for anyone with an implanted InterStim Therapy system. If lithotripsy must be used, the beam should not be focused within 6 inches (15 cm) of the neurostimulator.

Magnetic resonance imaging (MRI)

Medtronic recommends that an MRI should not be prescribed for anyone with an implanted neurostimulator or for anyone who has any part of an InterStim Therapy system implanted. Exposure to an MRI can potentially injure the patient or damage the neurostimulator.

The known potential risks are as follows:

- Induced electrical currents from the MRI to the InterStim Therapy system can cause heating, especially at the **lead** electrode site, resulting in tissue damage. Induced electrical currents can also stimulate or shock the patient.

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Note: This warning applies even if only a lead or an extension is implanted, it does not only apply to an implanted neurostimulator.

Factors that increase the risks of heating and injury include, but are not limited to, the following:

- High MRI Specific Absorption Rate (SAR) Radio-frequency (RF) power levels.
- MRI RF transmit coil that is near or extends over the implanted lead.
- Implanted leads with small surface area electrodes.
- Short distances between lead electrodes and tissue that is sensitive to heat.
- An MRI may permanently damage the neurostimulator, requiring it to be removed or replaced.
- An MRI may affect the normal operation of the neurostimulator. An MRI can also reset the neurostimulator to power-on-reset values requiring reprogramming by a trained InterStim Therapy **clinician**.

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- The neurostimulator can move within the implant pocket and align with the MRI field, resulting in discomfort or reopening of a recent implant incision.

In addition, the image details from MRI may be degraded, distorted, or blocked from view by the implanted InterStim Therapy system.

Patients treated with MRI should be closely monitored and programmed parameters verified upon cessation of MRI.

Radio-frequency (RF)/microwave ablation

Safety has not been established for radio-frequency (RF) or microwave ablation in patients with an implanted InterStim Therapy system. Induced electrical currents can cause heating, especially at the lead electrode site, resulting in tissue damage.

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Table B.1 Medical procedures: EMI-related warnings and effects

Medical procedure	Patient Device		Other possible effects			See guidelines
	injury	damage	Momentary increase in stimulation	Turns device on or off	Intermittent stimulation	
Bone growth stimulators	•	•	•		•	page 105
Defibrillation/ cardioversion	•	•	•		•	page 96
Dental drills and probes	•	•				page 105
Diathermy, therapeutic ^a	•	•			•	page 94
Electrocautery	•	•				page 97
Electrolysis		•			•	page 104
High-output ultrasonics/ lithotripsy		•				page 99
Laser procedures		•				page 104
Magnetic resonance imaging (MRI)	•	•	•	•	•	page 99

Table B.1 Medical procedures: EMI-related warnings and effects
(Continued)

Medical procedure	Patient Device injury damage	Other possible effects			See guidelines
		Momentary increase in stimulation	Turns device on or off	Intermittent stimulation	
Psycho-therapeutic procedures	•	•	•	•	page 106
Radiation therapy	•	•			page 104
Radio-frequency (RF) microwave ablation	•	•		•	page 101
Therapeutic magnets			•		page 88
Therapeutic ultrasound ^a	•	•		•	page 96
Transcutaneous electrical nerve stimulation (TENS)		•	•		page 105

^a Diathermy and therapeutic ultrasound procedures are contraindicated for patients who have an Interstim Therapy system. See "Contraindications" on page 94 for more information.

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PRECAUTIONS about medical procedures

The following equipment is unlikely to affect the InterStim Therapy system if the guidelines below are followed:

Electrolysis

The neurostimulator should be turned off, and the electrolysis wand should be kept at least 6 inches (15 cm) away from the InterStim Therapy system.

Laser procedures

The neurostimulator should be turned off and the laser should be directed away from the InterStim Therapy system.

Radiation therapy

High radiation sources such as cobalt 60 or gamma radiation should not be directed at the InterStim Therapy system. If radiation therapy is required near the system, **lead** shielding should be placed over the neurostimulator to help prevent damage.

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Transcutaneous electrical nerve stimulation (TENS)

TENS electrodes should not be placed so that current passes over any part of the InterStim Therapy system. If the patient feels that the TENS unit might be interfering with their neurostimulator, discontinue using the TENS until you can speak with a trained InterStim Therapy **clinician**.

Bone growth stimulators

The coils of an external magnetic field bone growth stimulator should be kept 18 inches (45 cm) away from the InterStim Therapy system. When a bone growth stimulator is used, the clinician should ensure that both the bone growth stimulator and neurostimulator are working as intended.

Dental drills and ultrasonic probes

The neurostimulator should be turned off and the drill or probe should be kept at least 6 inches (15 cm) away from the InterStim Therapy system.

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Psychotherapeutic procedures

Safety has not been established for psychotherapeutic procedures using equipment that generates **electromagnetic interference** (eg, electroconvulsive therapy, transcranial magnetic stimulation) in patients who have an implanted InterStim Therapy system. Induced electrical currents may cause heating, especially at the **lead** electrode site, resulting in tissue damage.

Other medical procedures

The following medical procedures are unlikely to affect the InterStim Therapy system:

- Magnetoencephalography (MEG)
- Positron Emission Tomography (PET) scans
- Computerized Axial Tomography (CT or CAT) scans
- Diagnostic **ultrasound** (eg, anorectal, carotid scan, doppler studies)

Note: To minimize potential image distortion, the neurostimulator should be

turned off and the transducer kept 6 inches (15 cm) away from the InterStim Therapy system.

- Diagnostic x-rays or fluoroscopy

Note: Tight pressure in the area of the neurostimulator can damage the neurostimulator or disconnect components of the InterStim Therapy system. This will require surgery to replace or repair the InterStim Therapy system. X-ray equipment should be adjusted so it does not squeeze the neurostimulator too tightly.

If the neurostimulator case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

Other system PRECAUTIONS

Component compatibility

For proper therapy, only components that are compatible with the InterStim Therapy system should be used. For a list of Medtronic-

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compatible components, contact Medtronic Technical Services. No claims of safety or efficacy are made about the compatibility of non-Medtronic components with Medtronic components.

Clinician programmer interaction with a cochlear implant

The external portion of the cochlear system should be kept as far away as possible from the **clinician programmer** or the cochlear implant should be turned off during programming to prevent unintended audible clicks.

Clinician programmer interaction with other active implanted devices

If the patient has a neurostimulator and another active implanted device, the radio-frequency signal used to program either device can reset or reprogram the other device, or the magnet in a cardiac programmer can activate magnetically controlled functions in the neurostimulator.

To verify that inadvertent programming did not occur, doctors familiar with each device should check the programmed settings before the patient is sent home from the hospital and after either device is programmed (or as soon as possible after these times).

Contact the appropriate doctor immediately if you notice that the patient has symptoms that could be related to either device or to the medical condition treated by that device.

Interaction with cardiac implantable devices

When a neurostimulator and an implanted cardiac device (eg, pacemaker, defibrillator) are required, the doctors involved with both devices (urologist, urogynecologist, cardiologist, cardiac surgeon) should discuss the possible interaction between the devices before surgery.

To minimize or prevent device damage or interactions between implanted devices:

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- The doctor should place the devices on the opposite sides of the body from one another.
- A trained InterStim Therapy **clinician** should program the neurostimulator to a bipolar configuration and a minimum rate of 60 Hz. The cardiac device should be programmed to bipolar sensing.

Possible affects of having both a cardiac device and an InterStim neurostimulator include the following:

- Defibrillation therapy from the implanted defibrillator can damage the neurostimulator.
- The electrical pulses from the InterStim Therapy system could affect the sensing operation of the cardiac device and result in inappropriate responses from the cardiac device.

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Neurostimulator disposal

An implanted neurostimulator should be removed before burial or cremation. In some

countries, removal of battery-powered implantable devices is required before burial because of environmental regulations.

The cremation process causes the battery to explode. Explanted devices should not be resterilized or reimplanted. Explanted devices should be returned to Medtronic for proper analysis and disposal.

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Appendix C Clinical trial results



There have been studies done on both the test **stimulation** and long-term implant of the InterStim system. This appendix explains the clinical trial results for the **urinary** control studies and the bowel control studies.

Urinary Control Clinical Trial Results

Patient study results for test stimulation

A study of patients showed that InterStim Therapy successfully treated certain bladder control problems.¹ A total of 581 patients underwent test stimulation, and 45% of them had a successful test. During the study, problems were experienced by 23.2% of patients.²

The problems were temporary and completely resolved shortly after the procedure. One problem required surgery to remove a broken lead tip. The problems were:

¹ Although the clinical data was collected using the Model 041830 Test Stimulation lead, the Model 3057 Test Stimulation lead has the same electrical characteristics as the Model 041830 lead. Therefore, the clinical study results are valid for both devices.

² Other adverse events included the following: affected equilibrium (1 patient), poor rubber pad adhesion (1 patient), and syncope (1 patient).

- Test stimulation lead moved (11.8% of patients)
- Undesirable changes in bowel or bladder activity (0.7% of patients)
- Infection or skin irritation (1.0% of patients)
- Some temporary pain (2.1% of patients)
- Technical problem with the device (3.7% of patients)
- Jolting or shocking sensation (0.1% of patients)
- Lead tip broke off (0.1% of patients)

Clinical trial results for implanted InterStim system for urinary control

In the Medtronic clinical trial, 219 patients were implanted with the InterStim Therapy system. Based upon the results of this 12-month clinical trial, Medtronic received FDA approval to offer InterStim Therapy system in the United States beginning in 1997.

Note: For this clinical trial, doctors used two types of leads, Models 3080 and 3886. Many

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doctors now use a new type of lead, Models 3889 and 3093, which are implanted using a minimally invasive technique.

Here are the results 12 months after surgery.

Urge incontinence¹

- Results showed an overall clinical success rate of 79% for **urge incontinence**.
- 45% of patients remained completely dry.
- 34% of patients reduced the number of wetting episodes by at least 50%.
- 70% of patients eliminated heavy leaking episodes. Prior to an implant of the InterStim Therapy system, 30 out of 38 patients experienced heavy leaking episodes.
- Results showed an overall clinical success rate of 79% for urge incontinence.

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¹ Based on a 12-month clinical trial of 38 patients who suffer from urge incontinence.

Urgency-frequency¹

- Results showed an overall clinical success rate of 64% for **urgency-frequency**.
- 33% of patients reduced the number of voids by 50% or more.
- 31% of patients reduced the number of voids from more than 7 times per day to normal (4-7 per day).
- 82% of patients improved the degree of urgency before voiding. Because urgency-frequency patients feel a strong urge to **void**, and void small amounts of urine each time, "success" means that patients increased the amount of urine voided each time and felt either the same or less urgency with each void.

Retention²

- Results showed an overall clinical success rate of 77% for retention.

¹ Based on a 12-month clinical trial of 33 patients who suffer from urgency-frequency.

² Based on a 12-month clinical trial study of 38 patients who suffer from retention.

- 61% of patients eliminated the use of **catheters**.
- 16% of patients reduced the amount of urine emptied from the bladder using a **catheter** by 50%.

Results may vary for each patient. You may or may not achieve the same level of relief as the patients who participated in the clinical trials. For information on recent clinical trial results, contact your doctor.

Reported adverse events

In this trial, 52%, or 113 patients, reported problems with the therapy. Problems ranged from minor concerns such as skin irritation to major concerns such as pain, infection, or device problems. Of these reported problems, 8% resolved without intervention; 38% required some medical treatment, but not surgery or hospitalization; and 54% required hospitalization or surgery to correct.

None of these problems resulted in permanent injury to patients. At the time the database was closed and results were measured, 9% of

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these problems were not solved or corrected. Following the trial, doctors continued to work with their patients to resolve the remaining problems.

Table C.1 lists problems that happened during the trial. The percentage indicates how likely it is that each event might happen.

For example, a 15.3% probability means there is a 1 in 7 chance that within the first year someone who has an InterStim Therapy system implanted could feel pain where the neurostimulator is placed.

Problems may be resolved with surgery, medical therapy such as drugs, or reprogramming. These events may also resolve over time, or remain unresolved. Thirty-three percent (1 out of 3) of the patients implanted had additional surgery to resolve a problem.

Table C.1 Clinical trial reported problems

Problem	Patients who reported the problem
Pain where the neurostimulator is placed	15.3%
New pain	9.0%
Suspected lead migration	8.4%
Infection	6.1%
Sensation of electric shock	5.5%
Pain at lead site	5.4%
Adverse change in bowel function	3.0%
Other	16.0% total ^a

^a The following problems each occurred less than 2% of the time: technical problem, suspected device problem, change in menstrual cycle, adverse change in voiding function, persistent skin irritation, suspected nerve injury, and device-rejection. The following problems each occurred less than 0.5% of the time: change in sensation of stimulation, grand mal seizure, hematoma or seroma, urinary hesitancy, neurostimulator turns on or off, lack of orgasm, lack of efficacy, numbness and tingling, foot/leg movement, strong anal sensation, unable to perceive stimulation, stress urinary incontinence, swollen feeling in abdomen, vaginal cramps, superficial connection, and possible skin perforation at neurostimulator.

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Post implant results at 5 years

Adverse Events

In this trial, approximately 69% of patients experienced 271 problems with the therapy after 5 years. Problems ranged from minor concerns such as pain, infection or device problems; 42% of patients required surgical intervention to resolve the problem. Most of the problems were because of pain at the neurostimulator site and lead migration. Thirty two (21% of) patients had one problem that required revision surgery at 5 years after initial implant.) Seventeen (11% of) patients had two problems that required revision surgery at 60 months after initial implant.

Table C.2 indicates how likely it is that each event might happen.

Problems may be resolved with surgery, medical therapy, such as drugs or reprogramming. These problems may also resolve over time, or remain unresolved.

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Table C.2 Clinical trial reported problems

Problem	Patients who reported the problem
New pain/undesirable change in stimulation	29.0%
Pain where the neurostimulator is placed	21%
Suspected device problem	10%
Suspected Lead migration	9.0%
Infection	9.0%
Pain at lead site	9.0%
Sensation of electric shock	8.0%
Adverse change in voiding function	7.0%
Technical problems during implant	5.0%
Other	35% total ^a

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- The following problems occurred less than 5% of the time. Adverse events classified as "other" by the investigator include the following (number of patients reporting): lack/loss of efficacy/stimulation benefit (10), pain (7 total: 2 back pain, 1 buttock lumbar, 1 left flank when bending, 1 vaginal pain with heavy lifting, 1 left leg, 1 around anus), device turning on and off (6), hematoma or seroma (5), battery depletion (4), persistent skin irritation (3), stimulation of foot/toe (3), cramping (2 total: 1 left foot, 1 vaginal and left buttock), decreased sense of stimulation (2), security turning stimulators on/off (2), too much effect around anus (2), two urinary tract infections (1), and 1 each of the following: black stool, bladder unstable, bowel perforation or peritonitis, change in CT results, device explant and replacement (reason not stated), device in magnet mode, resulting in no stimulation and requiring patient self-catheterization, extension connector implanted too deep, requiring corrective surgery, inability to turn device on, fever of unknown origin, interference with EKG, intermittent/incomplete retention, irritation on defecation, lack of efficacy due to lead migration, lack of orgasm, lead break, leg jerking while asleep, paresthesia right leg, persistent fever, pulse generator migration, pulse generator migration with bending, stimulation increased with flying, stimulation of leg resulting in pain, stimulation resulting in chest pain and irritation, stimulation felt at different spots, stimulation at pulse generator site, stimulator turned off by sewing machine, stress incontinence, suspected nerve injury, tightness at rectum, and wound incisional drainage.

After Medtronic received FDA approval to offer InterStim Therapy in the United States, Medtronic conducted another study to evaluate long-term (5 years) use of InterStim Therapy. 152 implanted patients were enrolled with this trial.

Here are the results 5 years after surgery.

Urge Incontinence¹

- 59% of patients had more than a 50% decrease in leaks per day.
- 71% of patients had more than a 50% decrease in heavy leaks per day.

Urgency-Frequency²

- 39% of patients had more than a 50% decrease in voids per day.
- 56% of patients had more than a 50% increase in urine eliminated at each void.
- 56% improvement in urgency.

¹ Based on a 5-year clinical trial of 61 patients who suffer from urge incontinence

² Based on a 5-year clinical trial of 18 patients who suffer from urgency-frequency

Urinary Retention¹

- 65% of patients had more than a 50% decrease in the number of self-catheterizations per day.
- 78% of patients had more than a 50% decrease in the amount of urine collected at each catheterization.

¹ Based on a 5-year clinical trial of 23 patients who suffer from urinary retention

Bowel Control Clinical Trial Results

Clinical trial results for test stimulation

InterStim Therapy for Bowel Control treats fecal incontinence (an accident or leaking involving stool). It should be used after you have tried more conservative treatments and they have not worked, or if you are not a candidate for more conservative treatments.

This therapy has helped many people who participated in the clinical trial with bowel control problems who did not respond to other treatments, such as change in diet, medication, or biofeedback.

Two hundred eighty-five (285) patients were enrolled in the study. Of these enrolled patients, 132 who met inclusion/exclusion criteria underwent test stimulation and 120 (91%) had a successful test (≥ 50 improvement in bowel control problems) and were implanted with the InterStim system.

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Reported Adverse Events

During the test stimulation phase, problems related to the device or the procedure were experienced by 23 (17.4%) patients. The most frequently reported problems were:

- Implant site pain in 5 patients (3.8%)
- Hematoma in 2 patients (1.5%)
- Broken lead in 2 patients (1.5%)
- Lead dislodgment/migration in 2 patients (1.5%)
- Skin irritation in 2 patients (1.5%)
- Leg pain in 2 patients (1.5%)
- Other types of adverse events reported in less than 1.5% of patients¹

¹ Additional adverse events were reported in less than 1.5% of patients (one patient per event) include: buttock pain, chest pain, constipation, device malfunction, diarrhea, discomfort, bruising, broken lead extension, loss of blood, fluid collection around neurostimulator, infection, drainage, nausea, pain, tingling/numbness, urinary incontinence, urinary retention, urinary tract infection, and vaginal pain.

Clinical study results for long-term therapy

In this trial, 120 patients were implanted with the InterStim Therapy System. Table C.3 shows the improvement categories in incontinent episodes per week from baseline to 12-months post implant using two kinds of analyses (Modified Worst-Case Analysis¹ and Completers Analysis²). With the modified worst-case analysis, 35.8% of patients achieved full continence of bowel movements, and a total of 73% of patients reported a 50% or greater reduction in the number of incontinent episodes per week. With the completers analysis, 40.6% of patients achieved full continence of bowel movements, and a total of 83% of patients reported a 50%

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¹ All 120 patients were included in this analysis. For 14 patients who did not complete the 12 month bowel diary, their baseline diary was used for the 12 month diary.

² Only 106 patients who completed bowel diaries both at baseline and at 12-months post implant were included in this analysis.

or greater reduction in the number of
incontinent episodes per week.

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Table C.3 Improvement Categories (Incontinent Episodes Per Week).

Improvement Categories (Incontinent Episodes Per Week)	Intent-to-Treat (Modified Worst-Case) Analysis (n=120)		Per Protocol (Completers) Analysis (n=106)	
	Number of Subjects	Percent of Subjects	Number of Subjects	Percent of Subjects
100%	43	35.8%	43	40.6%
75-99%	30	25.0%	30	28.3%
50-74%	15	12.5%	15	14.2%
1-49%	10	8.3%	10	9.4%
≤0%	22 ^a	18.3%	8	7.6%

^a This includes 14 subjects who did not complete the 12 month bowel diary; therefore, their baseline bowel diary was used as their 12 month bowel diary and thus did not show a decrease in bowel episodes per week.

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Table C.4 shows the average number of incontinent episodes per week, incontinent days per week, and urgent incontinent episodes per week as reported by patients at baseline and at 12-months post implant, using the same two kinds of analysis (Modified Worst-Case Analysis and Completers Analysis). With the modified worst-case analysis, on average the number of incontinent episodes per week decreased from 9.4 at baseline to 3.1 at 12-months. With the completers analysis, on average the number of incontinent episodes per week decreased from 9.2 at baseline to 1.9 at 12-months.

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Table C.4 Fecal Incontinence Symptoms at Baseline and 12-Months Post Implant

Fecal Incontinence Symptoms	Intent-to-Treat (Modified Worst-Case) Analysis (n=120)		Per Protocol (Completers) Analysis (n=106)	
	Baseline	12-Months	Baseline	12-Months
Average incontinent episodes per week	9.4	3.1	9.2	1.9
Average incontinent days per week	4.5	1.5	4.5	1.1
Average urgent incontinent episodes per week	5.0	1.7	4.9	1.2

Internal Anal Sphincter (IAS) Defect

The presence of an Internal Anal Sphincter (IAS) defect often implies that an obstetric tear has extended through the external anal sphincter (EAS) to involve the IAS. A disruption of the IAS may indicate a more severe injury. The success rate (proportion of patients reporting a 50% or greater improvement in incontinent episodes per week) among the 20 patients with an IAS defect was 65%, compared to 87% among the 86 patients without an IAS defect. This suggests that the presence of an IAS defect may be associated with reduced success; nonetheless, more than half of the patients (65%) with severe sphincter defect were still able to demonstrate effectiveness with the InterStim system.

Improvement in Quality of Life

Patients implanted with the InterStim system reported improvements in various aspects of their quality of life including lifestyle, coping/behavior, depression/self-perception, and embarrassment, at 12 months post implant.

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Patient perception of their bowel health, on average, doubled from baseline to a more favorable state at 12 months. Additionally, the leakage of gas, mucus, liquid and solid stool showed a significant decrease at 12 months. Use of minipads/panty liners and other forms of protective undergarment was significantly reduced during the follow-up period.

Reported adverse events

In this trial, 88 (73%) patients reported problems with the therapy. Problems ranged from minor concerns such as skin irritation to major concerns such as pain, infection, or device problems.

The majority of these adverse events resolved spontaneously, with medications, or with reprogramming.

- Implant site pain in 31 patients (25.8%)
- Tingling/numbness in 15 patients (12.5%)
- Implant site infection in 13 patients (10.8%)

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- Change in sensation of stimulation in 10 patients (8.3%)
- Urinary incontinence in 8 patients (6.7%)
- Diarrhea in 6 patients (5.0%)
- Adverse events reported in less than 5% of patients¹

¹ The following adverse events were reported in 5 patients per event (4.2%): constipation, neurostimulator programming error, pain, pain in limbs, and urinary tract infection. The following adverse events were reported in 4 patients per event (3.3%): back pain, buttock pain, anal pain, fluid around neurostimulator, and urinary retention. The following adverse events were reported in 3 patients per event (2.5%): pain around the tailbone, urge to empty bowel, erosion of the neurostimulator through the skin, incontinence, lead migration/dislodgment, neurostimulator battery depletion, skin irritation, therapeutic product ineffective, and urinary tract disorder. The following adverse events were reported in 2 patients per event (1.7%): inflammation of the bladder, redness under the skin, broken lead, frequent or urgent urination, muscle spasms, neurostimulator migration, pelvic pain, frequent daytime urination, and opening of the wound. The following adverse events were reported in 1 patient per event (0.8%): abdominal pain, abnormal feces, anal discomfort, anal disorder, joint pain, joint inflammation, chest pain, depression, skin infection, device malfunction, bruising, broken lead extension, hardening of feces, gas, frequent bowel movements, abdominal disorder, abdominal motility disorder, itching of female genitalia, hematoma, headache, lead electrical resistance, loss of sensitivity to pain or touch, discharge, fluid collection around neurostimulator, redness at implant site, implant site irritation, implant site swelling, incision site complication, difficulty falling or staying asleep, nausea, fever, rash, anal discharge, pain above tailbone, lower back/leg pain, pain in male genitalia, sensation of heaviness, sensory disturbance, tenderness, toe deformity, vaginal pain, vomiting, vaginal discomfort, wound, wound complication, pain/tingling, and tingling.

Out of 120 patients implanted with the InterStim system, 22 had at least one surgical revision or replacement. The cumulative probability of a patient needing surgical revision (including device replacement) was 10% at 12 months and 17% at 24 months. There were 3 deaths in the study, none of which were device related.

In addition to the risks normally associated with surgery, implantation, or use of a neurostimulator system includes, but is not limited to, the following risks:

- Wound infection
- Lead dislodgment/migration
- Adverse change in bowel or urinary function
- Neurostimulator movement
- Temporary change in sensation
- Erosion of the device through the skin
- Pain at implant site

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